



Diabetes: A
National Public
Health Priority
A National Strategy for Diabetes

2016-
2020

The aim of this strategy is to implement measures aimed at preventing diabetes, expanding treatment options and improving the integrated management of diabetes so as to prevent or postpone the onset of diabetes-related complications

FOREWORD

Diabetes is a common chronic condition in the Maltese population. It is for this reason that Government has made diabetes one of its key priorities.

Inkomplu ntejbu u nwessgħu s-servizzi li jingħataw lid-dijabetiċi

kemm fuq livell ċentrali kif ukoll bħala kura fil-komunita'.....

In November 2014 I had the pleasure to launch a consultation document containing a series of proposals that together will help us to address diabetes effectively at a national level. This document was the basis for a public consultation that ran until May 2015.

The feedback received was heartening and encouraging. The document was also reviewed by external experts who confirmed that our vision and strategy is on the right track.

Our aim remains that of seeking to reduce the impact that diabetes has on individuals, their families and society.

The updated document focuses on the initiatives that have been selected for priority action. We acknowledge that it is impossible to do everything at once but we are determined to implement a series of interventions that together will start to make a difference. The aim of this document is to provide a blueprint to keep us firmly focussed on achieving results.

We have already started with the process of expansion of the Government formulary for diabetes medicines. This issue came out loudly and strongly during the consultation and we have listened and acted. We intend to continue to implement further expansion in the coming years. However we are resolute in our determination to focus on prevention, education and awareness since we believe that this is the most effective strategy in the long-term.

I would like to thank all those who have contributed to the content of this strategy, who have provided feedback, who have given time and energy to participate in the consultation process. It is now time to work together to put our ideas into practice.

Diabetes has an impact on people. Diabetes has an impact on our health and social services. Let us join forces and work together to undertake a collective effort involving all of society to tackle diabetes in a comprehensive manner. I look forward to working with all those who are willing to collaborate in this national effort.

Chris Fearne

Parliamentary Secretary for Health

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GLOSSARY

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| BIRO | Best Information through Regional Outcomes (Diabetes Information system project) |
| BMI | Body Mass Index |
| CSII | Continuous Subcutaneous Insulin Infusion |
| CVD | Cardiovascular Disease |
| DHC | Paediatric Diabetes Healthcare |
| DNS | Diabetes Nurse Specialist |
| DPA | Directorate of Pharmaceutical Affairs |
| DPP | Diabetes Prevention Program |
| DPS | Finnish Diabetes Prevention Study |
| eGFR | Estimated Glomerular Filtration Rate |
| EHES | European Health Examination Survey |
| EHIS | European Health Interview Survey |
| ESRF | End Stage Renal Failure |
| EUCID | European Core Indicators in Diabetes |
| EUROPOP | European Population projection figures |
| GFL | Government Formulary List |
| GFLAC | Government Formulary List Advisory Committee |
| GIGT | Gestational Impaired Glucose Tolerance |
| GDM | Gestational Diabetes Mellitus |
| GP | General Practitioner |
| HWL | Healthy Weight for Life Strategy |
| IFG | Impaired Fasting Glucose |
| IGR | Impaired Glucose Regulation |

| | |
|--------|---|
| IGT | Impaired Glucose Tolerance |
| ICT | Information and Communication Technologies |
| ISPAD | International Society of Paediatric and Adolescent Diabetes |
| LSA | Learning Support Assistant |
| MDT | Multidisciplinary Team |
| MI | Myocardial Infarction |
| MONICA | Multinational MONItoring of trends and determinants in Cardiovascular disease study |
| NCD | Non-communicable disease |
| NSO | National Statistics Office |
| OPU | Orthotics and Prosthetics Unit |
| PACS | Picture Archiving and Communication System |
| PDS | Paediatric Diabetes Service |
| POYC | Pharmacy of Your Choice |
| T1DM | Diabetes Mellitus Type 1 |
| T2DM | Diabetes Mellitus Type 2 |
| WHO | World Health Organization |
| WTE | Whole Time Equivalent |

EXECUTIVE SUMMARY

Diabetes Mellitus is a chronic disease that occurs when the pancreas is unable to produce enough insulin, or when the body cells cannot make proper use of the insulin produced, due to reduced sensitivity. Diabetes is an important cause for morbidity in Malta with around 10 per cent of the population above 18 years estimated to be living with this condition, a proportion of whom are undiagnosed. The incidence in Malta is expected to continue rising in all age groups, making diabetes a growing health problem. Diabetes has a significant impact on the quality of life of persons with diabetes and their families, especially when complications arise. The high burden of diabetes among the Maltese population calls for a national diabetes strategy. The overall aim of this strategy is to emphasise prevention and early diagnosis of diabetes, expand treatment options and further develop the integrated care and management of diabetes so as to prevent or postpone complications. Support for persons with diabetes and their families at all stages is considered an important aspect of the service framework being proposed.

Many of the risk factors leading to Type 2 diabetes, which is the common form of diabetes, are modifiable. Examples are obesity, unhealthy diet, physical inactivity and smoking. Evidence has shown that in the case of diabetes prevention, measures do work and that the onset of diabetes can be prevented or postponed if a healthier lifestyle were to be adopted. Prevention strategies require a whole of society approach in order to succeed. A higher level of public awareness about diabetes and measures to avoid Type 2 diabetes is necessary. Educating the public about diabetes, its risk and seriousness and promoting a healthy lifestyle could potentially avert the projected increase in diabetes incidence.

Diagnosing diabetes in its early stages or in the so-called pre-diabetic stage may delay the onset of diabetes and is important to reduce the risk of complications. The provision of care for individuals with diabetes involves various professionals. The diabetes clinic at Mater Dei Hospital is the hub for specialist care of persons with diabetes. Over the years, a shared care programme has been developed in partnership with the health centres primarily to offer care and support for persons with uncomplicated Type 2 diabetes. This strategy proposes to continue to build on the strengths of the existing clinical care programmes whilst seeking to address the gaps that have been identified. In order to attain consistent high quality outcomes the government will continue to invest in trained human resources. This will enable strengthening of the multi-disciplinary team approach particularly in those professions where critical shortages are known to exist. Health care professionals will be empowered and equipped to offer care in line with a national service framework. The aim is to ensure that patients receive optimal care in all health care settings since it is recognised that the private sector also plays an important role in the care of persons with diabetes.

For high standards of care to be achieved, Government will increase its investment in innovative treatment using a phased approach. The key emphasis in both children and adults will be primarily geared towards preventing complications through risk factor modification and control. This will be complemented by setting up of screening and follow up facilitated by the necessary information systems, for the early detection of complications at a stage where they are amendable to effective intervention.

Patient self-management is a key skill to effectively manage and care for diabetes. It requires patients to understand and know their health condition and to be able to independently control their blood glucose levels. This strategy addresses self-management by placing the patients in the centre of healthcare. It includes actions on patient empowerment, education, health literacy, accessibility of medicines and supplies for self-monitoring. Government will work in partnership with NGOs to implement stronger patient empowerment. In order to tackle the burden of diabetes effectively, comprehensive and complete information regarding the epidemiology of the disease is necessary. The updated strategic plan is built on the proposal for consultation launched in November 2014. Priority initiatives have been identified taking into account the feedback received during the public consultation process. The Government is presenting the first ever national strategy for diabetes in line with its electoral programme proposal to bring about improvement in the quality of life for persons with diabetes and their families.

CHAPTER 1: INTRODUCTION TO THE NATIONAL DIABETES STRATEGY 2016-2020

WHAT IS DIABETES?

According to the World Health Organisation (WHO), 347 million people worldwide have diabetes and the prevalence is rising faster than expected (WHO, 2013). Diabetes Mellitus is a chronic disease that occurs when the body's response to insulin is diminished, either due to reduced sensitivity to Insulin, or due to reduced production of Insulin. Insulin is a hormone produced by the pancreas that regulates blood sugar concentration when this rises after a meal, or decreases while fasting. Large swings in sugar concentration are detrimental to health, and lead to both short- and long-term effects. Hyperglycaemia, or raised blood sugar, may seriously damage body tissues such as of the kidneys, nerves, and blood vessels especially when this has been ongoing for a long time. Hypoglycaemia or reduced blood sugar causes the brain to cease functioning properly, and unless corrected immediately may lead to coma and eventually death.

TYPES OF DIABETES MELLITUS

TYPE 1 DIABETES

This is caused by the body's immune system destroying insulin-producing cells in the pancreas. This leads to a reduction in the potential for the body to produce insulin requiring administration of insulin (injected).

TYPE 2 DIABETES

In this type of Diabetes, there is a gradual increase in resistance of the body's tissues to the effects of insulin. There is a more gradual onset than Type 1 diabetes (T1DM) and is most common in middle-aged and elderly, however it is becoming more common in younger people too (Rosenbloom, Joe, Young, & Winter, 1999).

There are a number of modifiable risk factors for Type 2 Diabetes (T2DM) including obesity, smoking and inactivity. Hence, apart from starting oral hypoglycaemic agents, first-line management includes dietary changes and exercise.

GESTATIONAL DIABETES

This is the onset of diabetes during pregnancy in an individual with no previously known diabetes but certain risk factors such as obesity and smoking. This is caused by insulin resistance during pregnancy and might herald the onset of T2 DM.

DIABETES IN MALTA

In 2010, a pilot European Health Examination Survey (EHES) was conducted in which blood glucose measurements were taken to estimate the prevalence of diabetes. 9.8% of the study population (aged 18 years and over) were found to have Diabetes. The prevalence of elevated blood glucose increased sharply after the age of 40. Between the ages of 41 and 60, 12.2% of the study sample had elevated blood glucose, while this rose to 21.6% of the population older than 60 (Directorate for Health Information and Research, 2010).

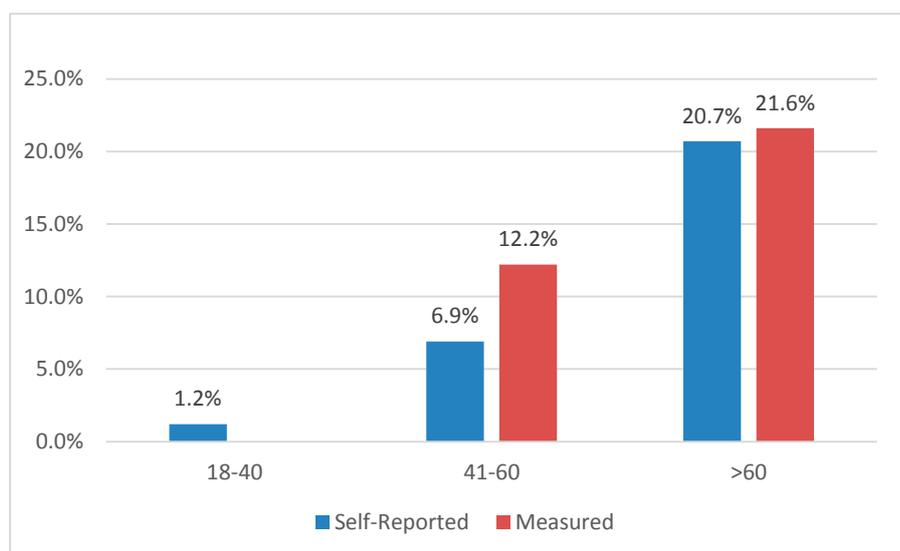


FIGURE 1: SELF-REPORTED (2008) AND MEASURED (2010) PREVALENCE OF ELEVATED BLOOD GLUCOSE BY AGE (Directorate for Health Information and Research, 2010)

According to the European Health Interview Survey (EHIS) conducted 2 years previously in 2008, the self-reported prevalence of Diabetes was 8%, and 6% of the population were taking medications for Diabetes (Department of Health Information and Research, 2008).

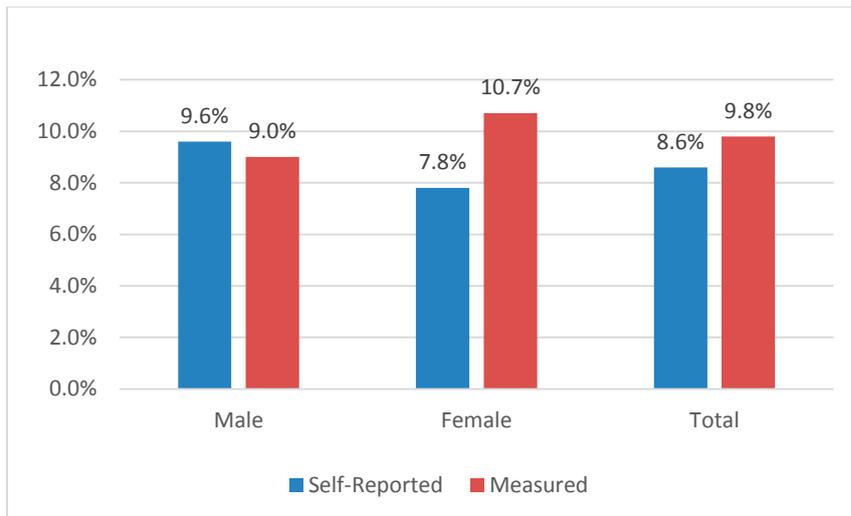


FIGURE 2: SELF-REPORTED (2008) AND MEASURED (2010) PREVALENCE OF ELEVATED BLOOD GLUCOSE BY GENDER (Directorate for Health Information and Research, 2010)

According to the International Diabetes Federation, 10.1% of all 20-79 year olds in Malta suffer from Diabetes. This places Malta in the first quartile within the European region.

The last population based prevalence study on diabetes was the MONICA study conducted under the auspices of WHO in 1984. This study had estimated prevalence of diabetes in persons aged 15+ in Malta at 7.7% (A. G. Schranz, 1989).

The above data, whilst having certain limitations, clearly shows diabetes to be a relatively large and still growing health problem in Malta.

MORTALITY DUE TO DIABETES

In 2013, the Standardised Mortality Rate due to Diabetes was 13 per 100,000 for females, and 19 per 100,000 for males. The average age of death due to Diabetes Mellitus was 72.2 years in males and 77.9 years in females, compared to the general population's average age at death of 73.5 years and 79.3 years respectively (Directorate for Health Information and Research, 2013).

DIABETES IN PREGNANCY

In 2014, there were 18 mothers who were reported as being Insulin Dependent before their pregnancy while there were 6 mothers reported with Non-Insulin Dependent diabetes prior to pregnancy. There was a total of 135 mothers registered with impaired glucose tolerance or gestational diabetes (Directorate of Health Information and Research, 2014).

Gestational Diabetes is the second-most frequent pathology encountered during pregnancies between 2001 and 2010 (2.4% of maternities) (Department of Health Information & Research, 2012).

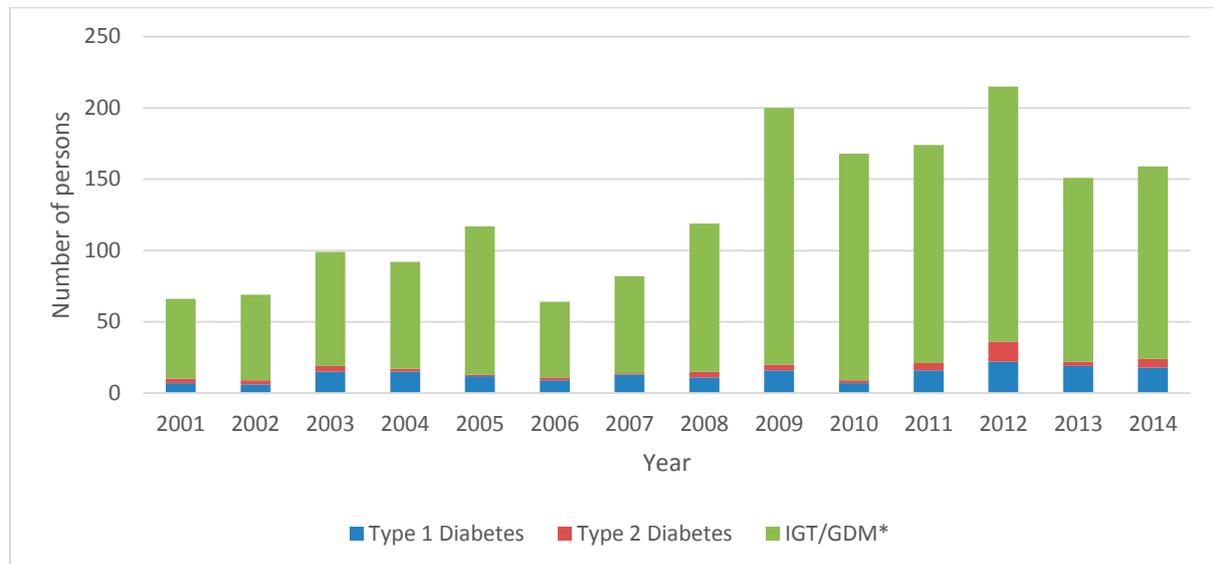


FIGURE 3: MATERNAL PATHOLOGY DURING PREGNANCY (Directorate of Health Information and Research, 2014) (* IMPAIRED GLUCOSE TOLERANCE OR GESTATIONAL DIABETES)

HOSPITAL STAY

The average length of stay in hospital for Diabetes Mellitus is the highest in the EU since 2011. In 2014, it was 14.6 days while the EU average was 8.4 days 2014 (EUROSTAT, 2015).

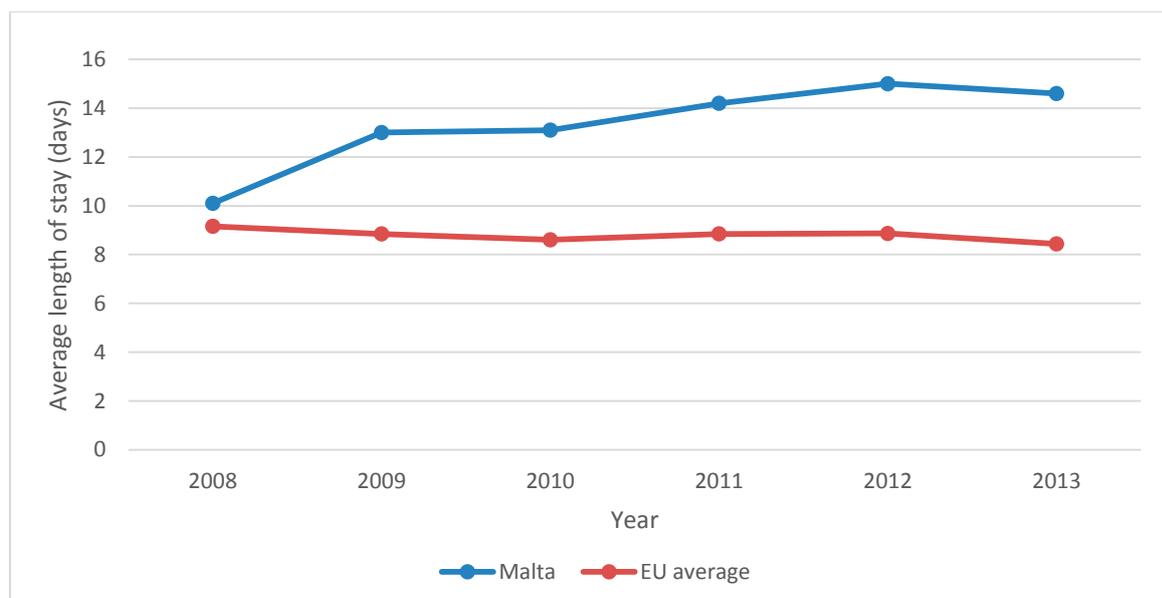


FIGURE 4: IN-PATIENT AVERAGE LENGTH OF STAY (DAYS) FOR PATIENTS WITH DIABETES MELLITUS COMPARING MALTA TO EUROPE (EUROSTAT, 2015)

UNCONTROLLED DIABETES

The age and sex-standardised rate of hospital admissions due to uncontrolled diabetes was 160 per 100,000 population which is comparable to the EU15 average of 159 per 100,000 in 2009 (OECD, 2012).

RISK FACTORS FOR DIABETES

AGE

Since T2DM is commonly diagnosed in middle age and is most prevalent in older people, the changing demographics will have an impact on the prevalence of Diabetes.

SOCIO-ECONOMIC FACTORS

Factors such as obesity, physical inactivity, unhealthy diet, smoking and poor blood pressure control are all associated with increased risk of developing diabetes. These are more prevalent in individuals suffering from social deprivation and are hence linked (Wilkinson & Marmot, 2003).

MODIFIABLE RISK FACTORS

Obesity: When compared to EU member states, Malta has the highest rate of obesity amongst males and the third highest rate amongst females. 69% of males and 49.1% of females were overweight and obese (Department of Health Information and Research, 2008).

Unhealthy diet: The Health Promotion & Disease Prevention Directorate is in the process of conducting a National Food Consumption Survey which will give a good indication of Maltese eating habits. Based on previous surveys, the national obesity strategy has six targets for nutrition which include: reducing the frequency of intake of processed meats, sweets, pastries and sugared soft drinks, increasing the intake of fish and vegetables, and reducing the mean daily intake of animal fat (Superintendence of Public Health, 2012).

Physical Inactivity: The 2002 and 2005 *Eurobarometer* studies on Physical Activity and Health and Food respectively report Malta as scoring the lowest in a comparison undertaken with the EU-15 (2002) and EU-25 (2005) member states for the number of days of moderate and vigorous physical activity, lowest duration of physical activity during the day and lowest average walking time during the week (EUROSTAT, 2015).

Smoking: 19.2% of the Maltese population aged 15 or older smoke daily (EU average 23.9%). (Department of Health Information and Research, 2008; EUROSTAT, 2015) In the 2007

European School Survey Project on Alcohol and Other Drugs study, conducted among Form 5 students, 26% of children reported smoking cigarettes in the previous 30 days. 3.4% of children have their first cigarette when less than 9 years old and the age at which the highest number of children smoked their first cigarette is 14 years (*European School Survey Project on Alcohol and other Drugs, 2007*).

According to the latest Health Behaviour in School Children study, Malta scored third from the top in terms of 13-year-olds who smoke at least once (11% of girls and 9% of boys)(WHO Europe, 2006).

HEALTH IMPACT OF DIABETES

GENERAL EFFECTS ON HEALTH AND WELLBEING

Diabetes is associated with a variety of other conditions affecting health. In fact, local data from the Health Interview survey reveals that the age-adjusted means of both the Mean Health Index (Figure 5) and the Mean Vitality Index score (Figure 6) are significantly lower in people with diabetes when compared to those without (self-reported) (Department of Health Information and Research, 2008).

Another measure of morbidity caused by Diabetes is the self-reported need for prescribed medications in diabetics versus non-diabetics, after the diabetic medication itself is excluded. While 55% of male diabetics are on some prescribed medication, only 35% of non-diabetics are. This difference is slightly smaller in females but still significant (Department of Health Information and Research, 2008) (Figure 7).

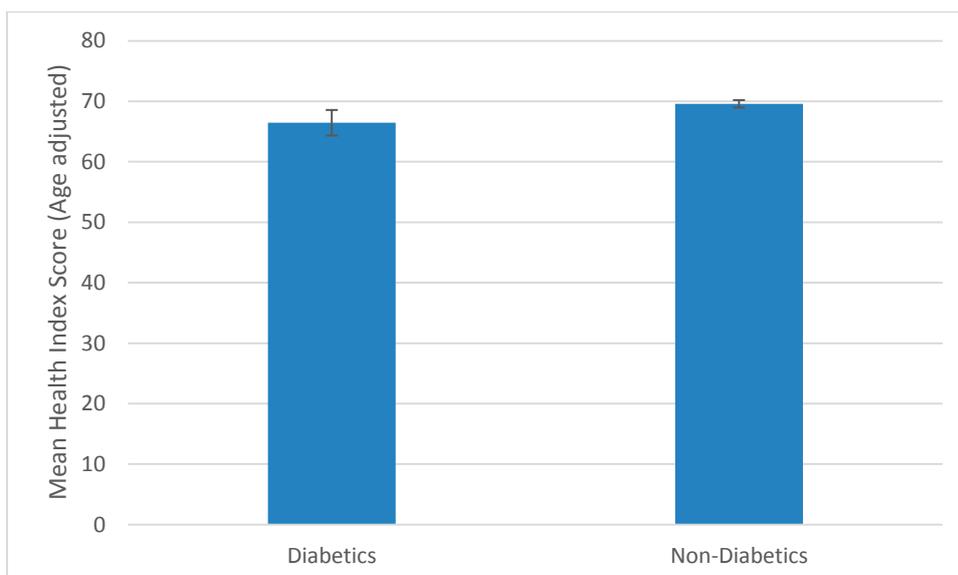


FIGURE 5: MEAN HEALTH INDEX SCORE (AGE-ADJUSTED) IN PEOPLE WITH AND WITHOUT DIABETES (Department of Health Information and Research, 2008)

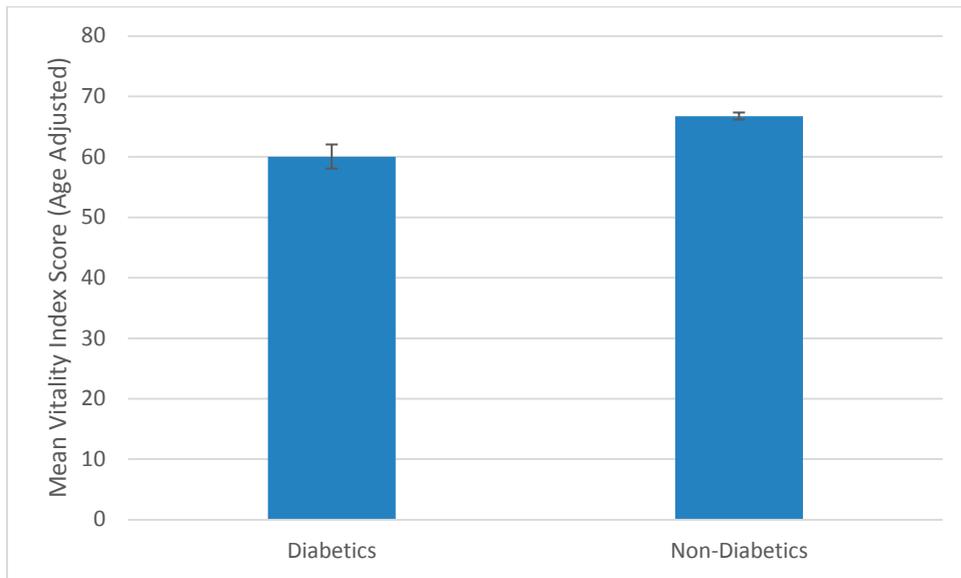


FIGURE 6: MEAN VITALITY INDEX SCORE (AGE-ADJUSTED) IN PEOPLE WITH AND WITHOUT DIABETES(Department of Health Information and Research, 2008)

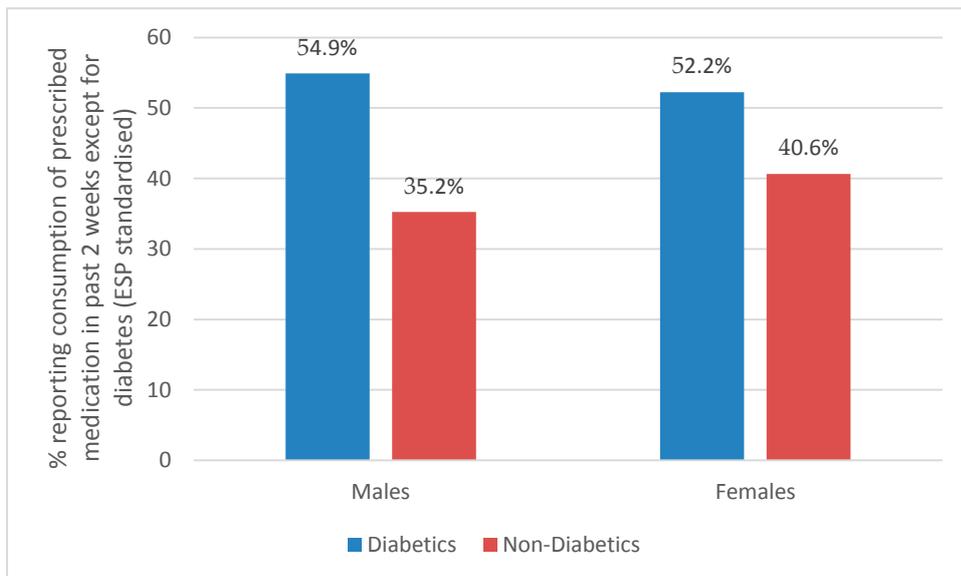


FIGURE 7: PROPORTION OF PEOPLE REPORTING CONSUMPTION OF PRESCRIBED MEDICATION IN THE PAST TWO WEEKS EXCEPT FOR DIABETIC MEDICATION (ESP STANDARDISED) IN DIABETICS VS. NON-DIABETICS BY GENDER (Department of Health Information and Research, 2008)

CARDIOVASCULAR DISEASE

Damage to arteries occurs in the presence of prolonged high glucose concentrations. This leads to a variety of cardiovascular diseases such as heart disease, stroke and peripheral vascular disease. People with diabetes have about twice the risk of developing a range of cardiovascular diseases, compared with those without diabetes, (Sarwar et al., 2010) and are

likely to die due to them. Cardiovascular disease is a major cause of death and disability in people with diabetes, accounting for 44 per cent of fatalities in people with Type 1 diabetes and 52 per cent in people with T2DM (Morrish, Wang, Stevens, Fuller, & Keen, 2001). Local data also shows that persons with Diabetes have a higher all-cause mortality rate after a myocardial infarction, than persons without diabetes (Gruppetta, Calleja, & Fava, 2010). In addition, people with T2DM have a two-fold increased risk of stroke within the first five years of diagnosis compared with the general population (Jeerakathil, Johnson, Simpson, & Majumdar, 2007).

KIDNEY DISEASE

The damage caused by high blood sugar concentrations also affects small vessels in the kidneys. They start working less efficiently which may eventually result in kidney failure. Keeping blood glucose levels as near normal as possible and blood pressure well controlled can greatly reduce the risk of kidney disease developing as well as other diabetes complications (Stratton et al., 2000). Despite this, diabetes is the single most common cause of end stage renal disease, (Locatelli, 2004) and around one in three people with T2DM eventually develops overt kidney disease (Remuzzi, Benigni, & Remuzzi, 2006).

Kidney disease is the second most common cause of death in diabetics, accounting for 21 per cent of deaths in T1DM and 11 per cent of deaths in T2DM (Morrish et al., 2001).

EYE DISEASE

Blood vessels in the retina of the eye can also be damaged. This leads to compromised vision and may even lead to blindness if untreated (Retinopathy). Within 20 years of diagnosis, nearly all people with T1DM and almost two thirds of people with T2DM (60 per cent) have some degree of retinopathy, and people with diabetes are 10 to 20 times more likely to go blind than people without diabetes (Infeld & O'Shea, 1998). People with diabetes are also twice as likely to suffer from cataracts or glaucoma as the general population (Ederer, Hiller, & Taylor, 1981).

The Health Interview Survey in 2008 asked respondents to state whether they could recognise a face 4 metres away, or read a newspaper as a measure of short-/long-sightedness respectively. (Figure 8, Figure 9) Diabetic subjects were found to be more likely to report having a lot of difficulty or even being completely unable to do so than non-diabetics (Self-reported) (Department of Health Information and Research, 2008) ($p < 0.05$).

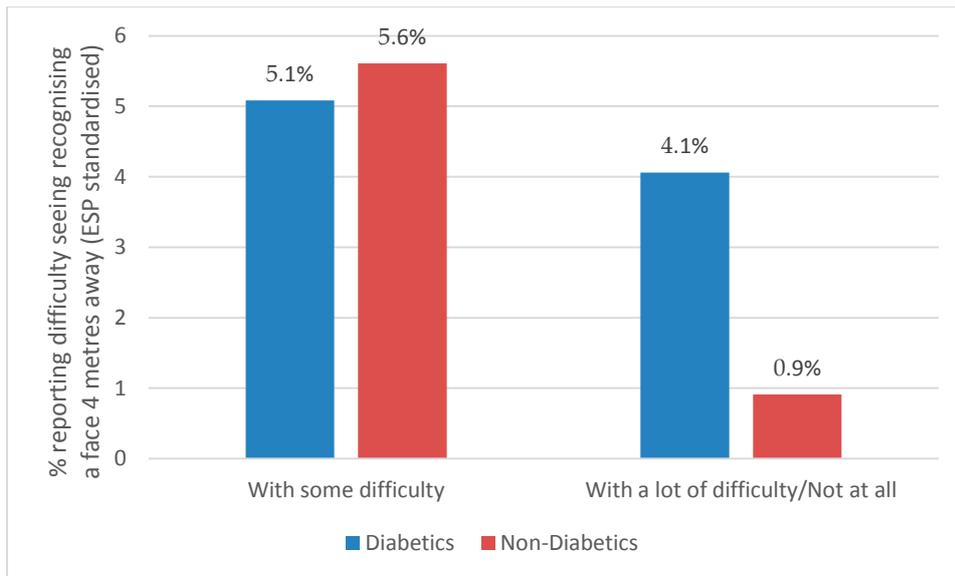


FIGURE 8: PROPORTION OF PEOPLE REPORTING ABILITY TO RECOGNISE A FACE 4 METRES AWAY (ESP STANDARDISED) IN PEOPLE WITH AND WITHOUT DIABETES

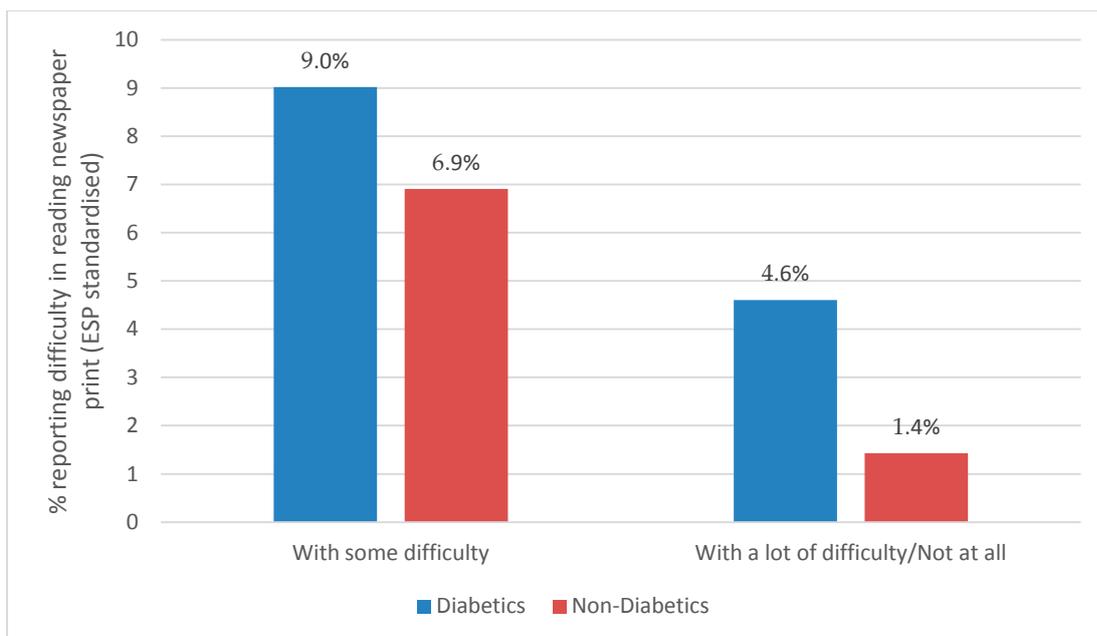


FIGURE 9: PROPORTION OF PEOPLE REPORTING ABILITY TO READ A NEWSPAPER (ESP STANDARDISED) IN DIABETICS VS. NON-DIABETICS

AMPUTATION

The biggest cause of amputations in persons with diabetes is due to peripheral artery disease. Worldwide, the rate of leg amputations in people with diabetes is over 15 times higher than in people without diabetes (A. J. M. Boulton, 1997). It is a cause of great morbidity and also a risk factor for premature death since up to 70 per cent of people die within five years of having an amputation as a result of diabetes (Schofield et al., 2006). In

Malta, 74% of persons who suffer a major amputation have diabetes (Amputee Database 2015).

MENTAL HEALTH

Emotional health and wellbeing can be affected by coping with diabetes and as a side effect of some medication.

The prevalence of depression is approximately twice as high in people with diabetes as it is in the general population (Katon et al., 2004).

Locally, people with diabetes are more likely to report symptoms of chronic anxiety or depression when compared to non-diabetics (Self-reported) (Figure 10) (Department of Health Information and Research, 2008).

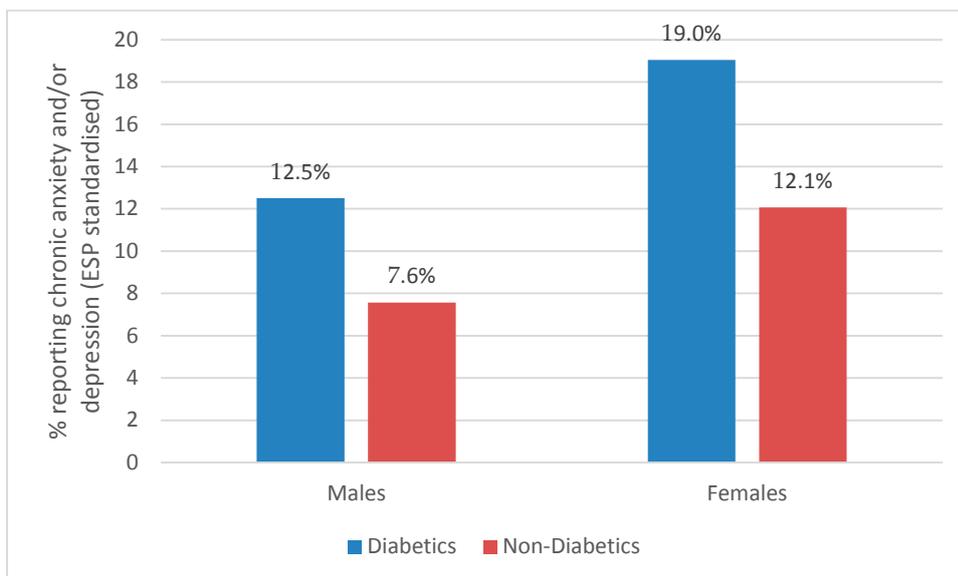


FIGURE 10: PROPORTION OF PEOPLE REPORTING CHRONIC ANXIETY AND/OR DEPRESSION (ESP STANDARDISED) IN PEOPLE WITH AND WITHOUT DIABETES (Department of Health Information and Research, 2008)

NEUROPATHY

Due to the damage to nerves that diabetes causes, some patients suffer from chronic nerve pain.

Neuropathies (or nerve damage) may affect up to 50 per cent of patients with diabetes (A. J.M. Boulton, 2005), which may lead to Charcot deformities which impact greatly on the quality of life.

The same neuropathy can result in erectile dysfunction. The reported prevalence of erectile dysfunction is between 35 per cent and 90 per cent among men with diabetes (Malavige & Levy, 2009).

ORAL HEALTH

Current evidence shows that there is a bi-directional relationship between diabetes and periodontal disease and that periodontitis may be associated with increasing glycaemia in people who do not have diabetes. Type 2 Diabetes is itself a risk factor for periodontitis.

COMPLICATIONS IN PREGNANCY

A foetus of a pregnant mother who is also a diabetic or develops diabetes during pregnancy is at a greater risk for complications such as macrosomia (excessive birth-weight) which may lead to complications during labour, neonatal hypoglycaemia and stillbirth (González-Quintero et al., 2007). Uncontrolled or unrecognised diabetes in early pregnancy can also lead to congenital malformations and miscarriages.

PROJECTIONS (FUTURE HEALTH PROFILE)

According to the latest projections by the International Diabetes Federation, the local prevalence of Diabetes is expected to rise unless drastic action is undertaken to address this. The rise in prevalence together with Malta's changing demographics also means that Maltese diabetics will get older and hence more prone to morbidity (International Diabetes Federation, 2013).

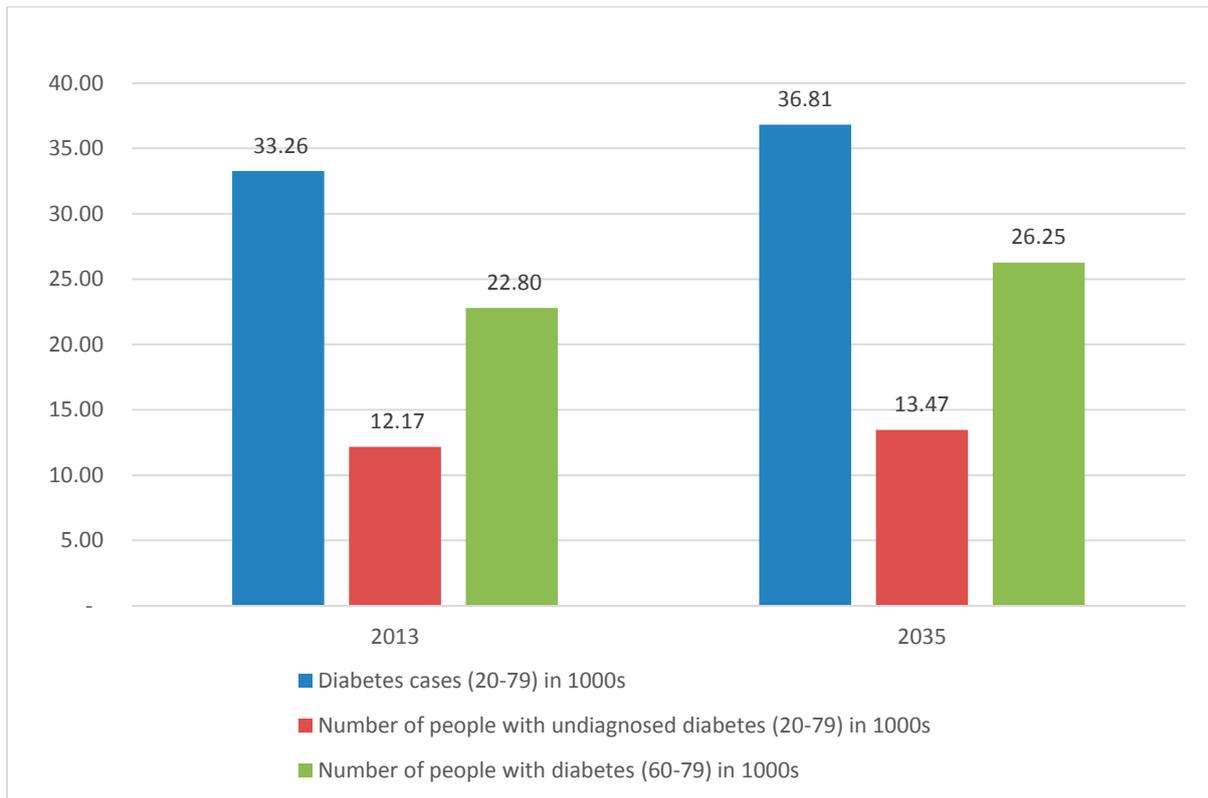


FIGURE 11: IDF PROJECTIONS FOR NUMBER OF DIABETES CASES (TOTAL, UNDIAGNOSED AND IN 60-79 YEAR AGE GROUP) IN 2035 (International Diabetes Federation, 2013)

Figure 12 shows the local projected prevalence of diabetes. This was produced by applying the current age-standardised rates to NSO's projected population demographics.

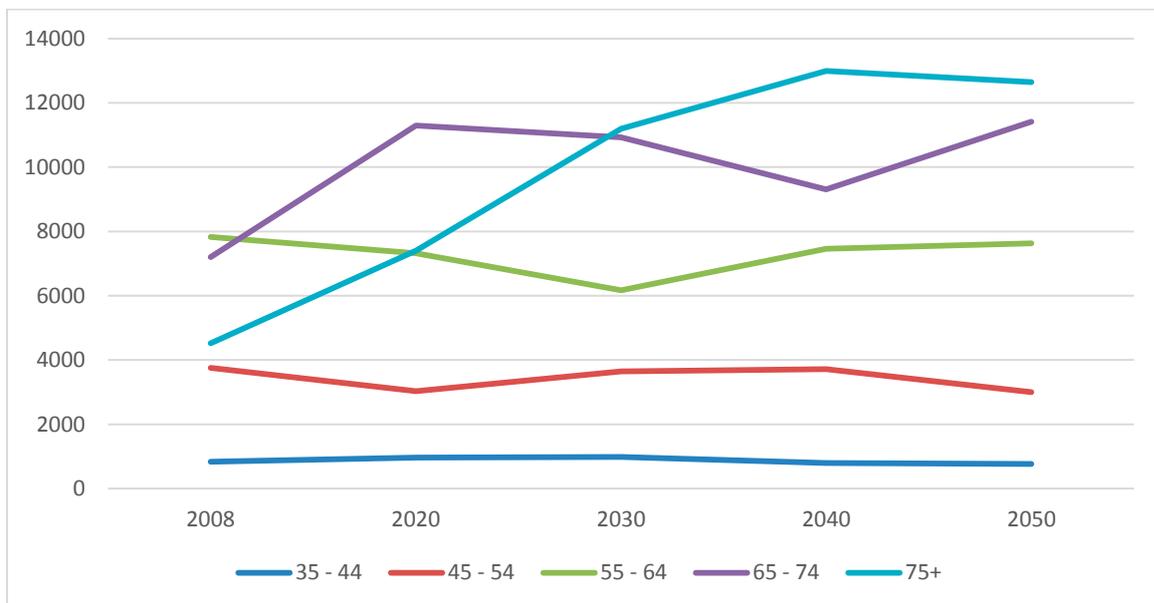


FIGURE 12: PROJECTED NUMBER OF PERSONS WITH DIABETES BY AGE GROUP. (Calleja, 2005)

NOTE: Projections assume that the age specific prevalence of self-reported diabetes remains the same from that reported in 2008. Projection calculated using 2010EUROPOP population figures for Malta.

COSTS

There are three categories of costs associated with diabetes:

Direct costs: Diabetes is costly for the health care systems because of its chronic nature and particularly because of the gravity of its complications.

Indirect costs: Diabetes causes a loss of productivity because of disability, sick leave, early retirement and premature death. These costs are borne both by firms and by insurance companies. Indirect costs are often higher than direct costs. **Intangible costs:** diabetes influences the quality of life of patients (suffering, anxiety, and discrimination sometimes). It can also affect their social life and their leisure time. Their mobility can also be reduced because of the disease.

Diabetes complications require hospitalisation most of the time. 50% of people with diabetes suffer from at least one complication. Hospitalisation represents the biggest proportion of the direct costs. It implies admission to hospital, laboratory analysis, the work of medical staff, specific therapies, and investments to assure the best quality of care for affected people. The length and the frequency of this hospitalisation also increase the costs on health systems. By contrast, drug costs (insulin, anti-diabetic drugs) to treat T2DM are relatively low. In conclusion, diabetes complications represent a huge cost for health care systems.

LOCAL COSTS

In Malta, the annual excess cost for hospital, primary care and specialist visits for persons with diabetes versus those without diabetes has been calculated using EHIS 2008 data. It is estimated to be at least €9 million, the bulk of which is due to more frequent and longer inpatient stays.

THE RATIONALE FOR A NATIONAL DIABETES STRATEGY FOR MALTA

Diabetes is an important cause of morbidity in the Maltese population. Its incidence is rising in all age groups. Diabetes has a significant impact on the quality of life of the individuals affected as well as their families. Furthermore, diabetes is an economic burden to society.

Some types of diabetes are preventable. Prevention strategies require a whole of society approach as is proposed in the WHO health policy Health 2020. Persons with diabetes have the potential to lead an active and fulfilled life. The support from society in terms of provision of high quality health care that is free at the point of use as well as removal of

barriers for engagement in work and leisure activities are important aspects of any diabetes strategy.

The high prevalence of diabetes in Malta warrants a national strategy. Whilst acknowledging and building upon the existing strengths, a national strategy allows us to focus on the gaps and propose measures to address them.

This will ensure coordinated action from health authorities, health care providers, health care professionals, patients and civil society in order to bring about a coordinated and consistent approach to diabetes prevention and care in Malta. In November 2014, Government published a draft strategy as a proposal for consultation. Following the feedback obtained during the public consultation process as well as the consultation that took place through the Parliamentary Working Group on Diabetes, Government has selected the priority initiatives for implementation over the next five years. These measures need to be implemented in partnership with all of society. This document largely builds upon the proposal issued in November 2014 since the feedback received during the consultation process indicated that there is a broad consensus on the proposed areas for action.

This first ever national diabetes strategy for Malta forms part of a series of health policies geared towards reduction of the burden of chronic non-communicable disease in society within the overarching framework of the National Health Systems Strategy.

CHAPTER 2: CURRENT SERVICE PROFILE FOR DIABETES

PROVISION OF CLINICAL SERVICES FOR DIABETES

All adult persons with diabetes irrespective of the aetiology and classification of their diabetes have access to specialist care provided within the diabetes clinic at Mater Dei Hospital. This clinic has been established for several decades previously at St Luke's Hospital and has been the reference point for all health care professionals and patients with regards to diabetes care offering services in line with International recommendations and standards for the management of patients with diabetes. Services are provided by specialised doctors, nurses and allied health professionals both on an outpatient and inpatient basis. Adults with T1DM, gestational diabetes, maturity onset diabetes of the young (MODY) and other rare types of diabetes as well as persons with complications from T2DM are all seen within the specialist clinics at Mater Dei Hospital since this is the appropriate clinical setting to care for these conditions. Children with diabetes are seen by a Consultant Paediatrician and Endocrinologist at the Children Outpatients.

When complications develop, other professionals are involved in the care of the person with diabetes depending on the nature of the complication. Ophthalmologists, renal physicians, vascular surgeons, cardiologists, physiotherapists, occupational therapists, podiatrists, and tissue viability nurses are key in the care of persons with diabetes who develop complications.

Over the past few years in order to meet the increasing demand as the prevalence of diabetes increases as a result of the demographic transition and other factors, as well as to devolve management as much as possible towards a primary care setting, a shared care diabetes program has been developed between Mater Dei Hospital as the specialist referral centre for all adult persons with diabetes and the health centres in primary care. In this shared care programme, primarily patients with uncomplicated T2DM are seen by a General Practitioner (GP) with a special clinical interest in primary care. Patients are also seen at prescribed time intervals by the specialist in diabetes and fast track referral scheme are in place to allow patients to be seen in between scheduled specialist appointments should the necessity arise.

Services to prevent eye complications through preventive retinal photography have been in place in a hospital setting for several years. More recently funduscopy cameras have also been installed in the community. Likewise, podiatrists offer foot screening, examination and management in both the hospital and community settings.

Currently, persons with diabetes in Malta can choose to be managed either through the public health sector or through the private sector. In the private sector patients are managed by their private GP or by their private diabetes specialist through a system of professional referral as the need arises. The significant contribution of private primary care in the Maltese health care system means that for a number of patients private primary care providers play a key role in the care of persons with diabetes. In many cases, a combination of service providers may be responsible for care of persons with diabetes across hospital and primary care and across public and private settings.

All persons with diabetes are also encouraged to attend structured diabetes education sessions carried out by diabetes nurses, doctors, dietitians and podiatrists. Sometimes referral for psychological review is also required.

Seamless communication and coordination of all aspects of patient care therefore represent a particular challenge in the management of diabetes which requires the specialised input of several health care professionals.

UTILISATION OF SERVICES

The Diabetes Clinics in Health Centres are mostly run by Family Doctors with a special interest and training in Diabetes. The number of attendances has been steadily increasing over the years (Figure 13). Persons with Diabetes are seen in a holistic manner, and a number of routine investigations and examinations are performed at least every 6 months. Persons with Diabetes are referred to the clinics by referral from Family Doctors in the community (both public and private), and also from Mater Dei Hospital.

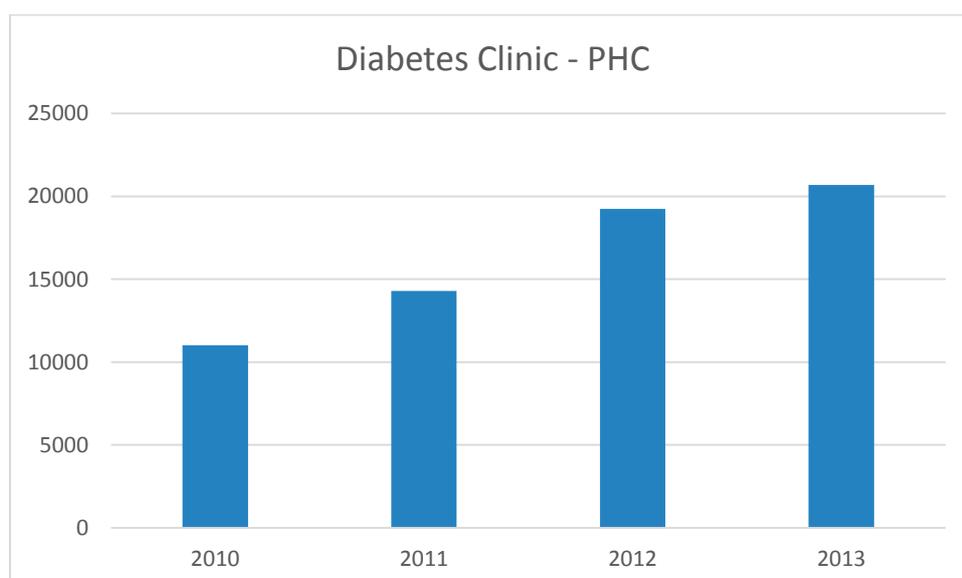


FIGURE 13: NUMBER OF ATTENDANCES AT THE DIABETES CLINICS IN PRIMARY HEALTH CARE (Directorate of Health Information and Research, 2013)

They are also referred once a year for podiatry and ophthalmic assessment at the Health Centres that offer Podiatry and Ophthalmology services.

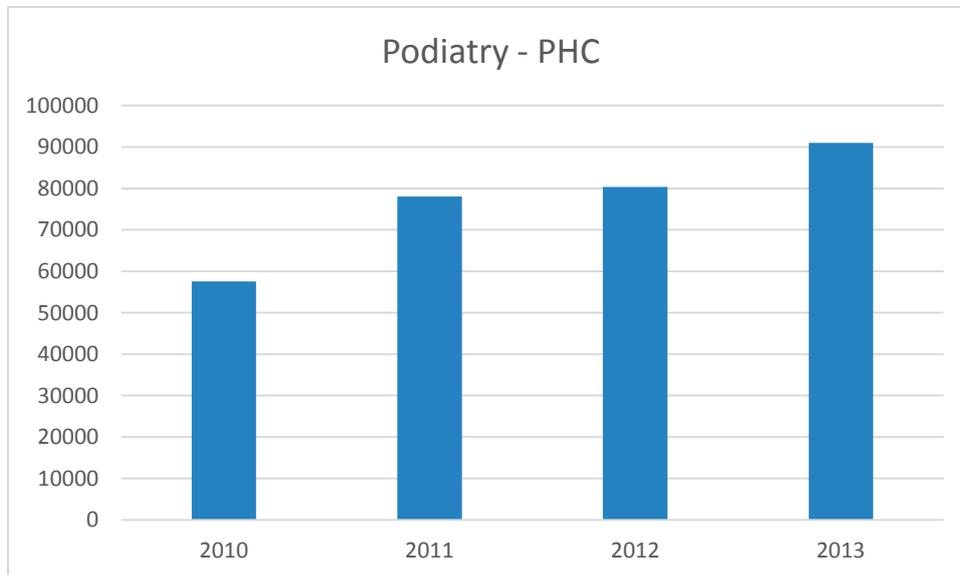


FIGURE 14: NUMBER OF ATTENDANCES AT THE PODIATRY CLINICS IN PRIMARY HEALTH CARE (Directorate of Health Information and Research, 2013)

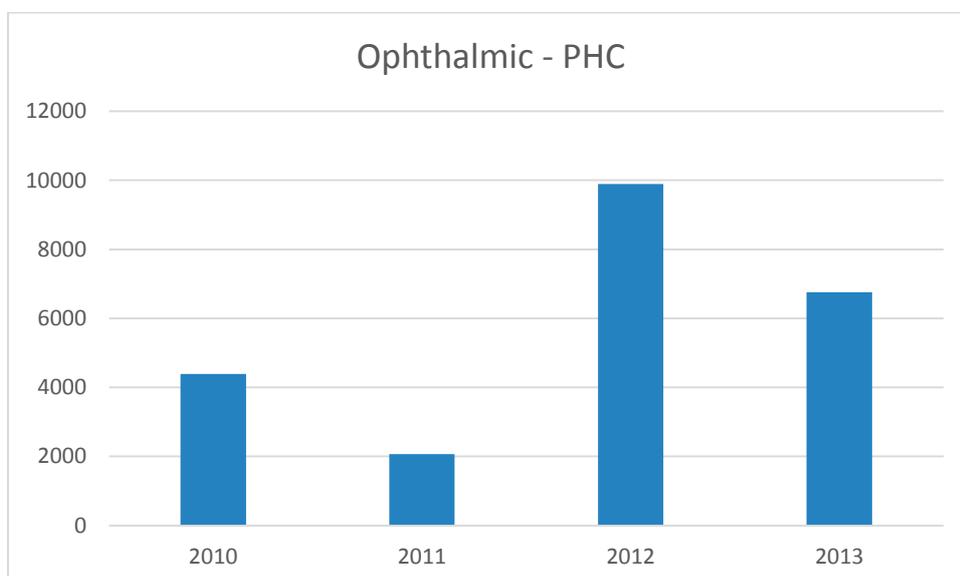


FIGURE 15: NUMBER OF ATTENDANCES AT THE OPHTHALMIC CLINICS IN PRIMARY HEALTH CARE (Directorate of Health Information and Research, 2013)

Currently, every person who attends the Diabetes Clinic in the community is reviewed by a diabetes specialist at a prescribed time interval depending on the clinical requirements. The clinics at Mater Dei Hospital are consultant-led. There are currently four Consultant Endocrinologists (and one part-time) who each run a Diabetes Clinic to deal with the ever-increasing number of referrals (Figure 16).

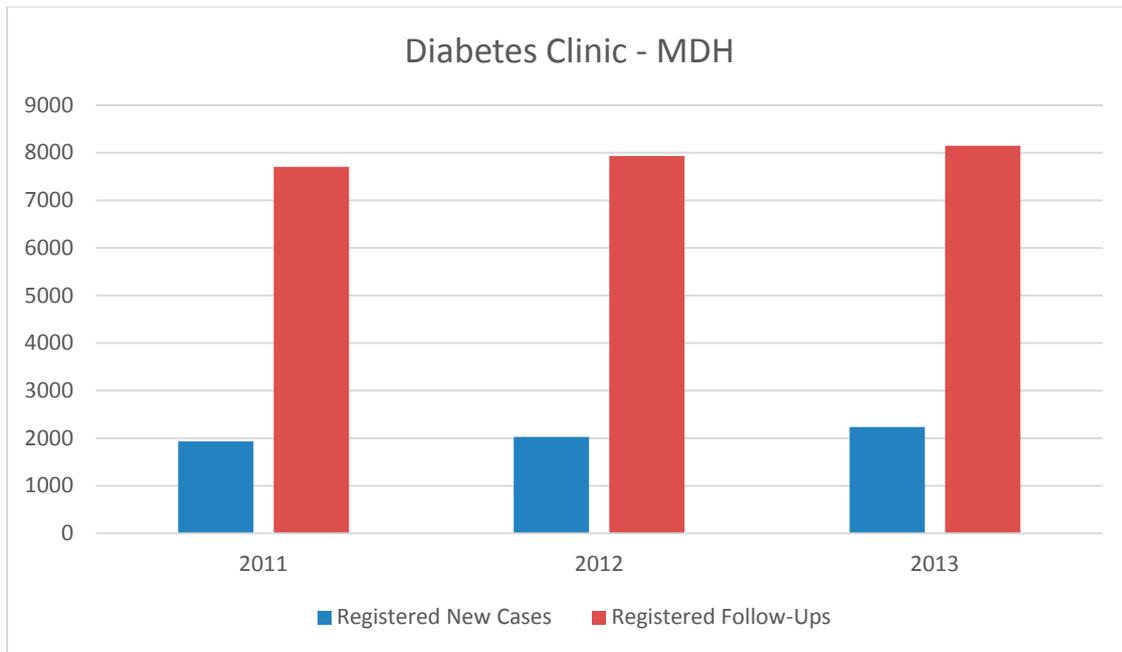


FIGURE 16: NUMBER OF ATTENDANCES AT THE DIABETES CLINIC AT MATER DEI HOSPITAL (Directorate of Health Information and Research, 2013)

Diabetes Awareness Sessions at Mater Dei Hospital are organised by three Practice Nurses specialised in Diabetes.

There are also Diabetic Retinopathy and Podiatry clinics at Mater Dei Hospital, who see cases referred from the consultant clinics, other healthcare providers, and also self-referrals.

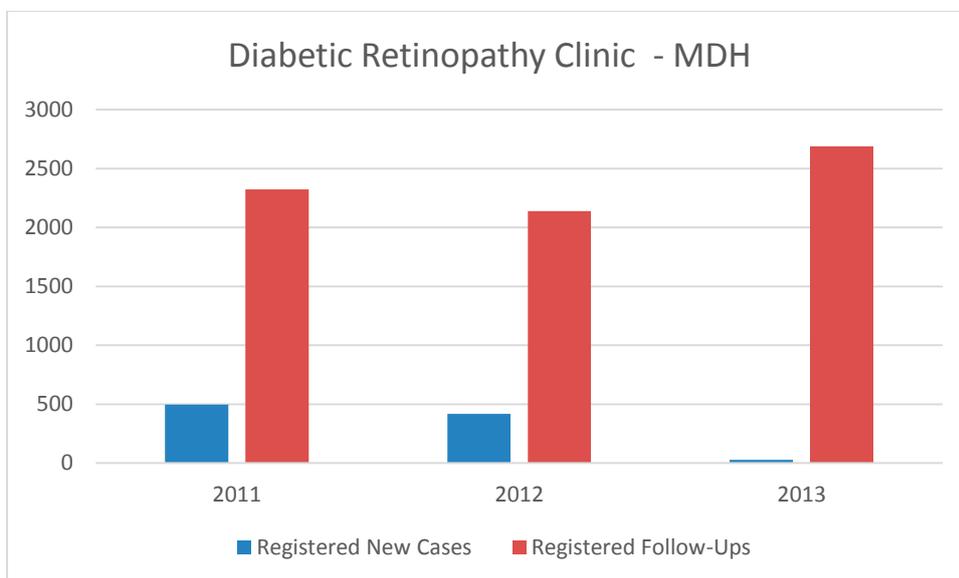


FIGURE 17: NUMBER OF ATTENDANCES AT THE DIABETIC RETINOPATHY CLINIC AT MATER DEI HOSPITAL (Directorate of Health Information and Research, 2013)

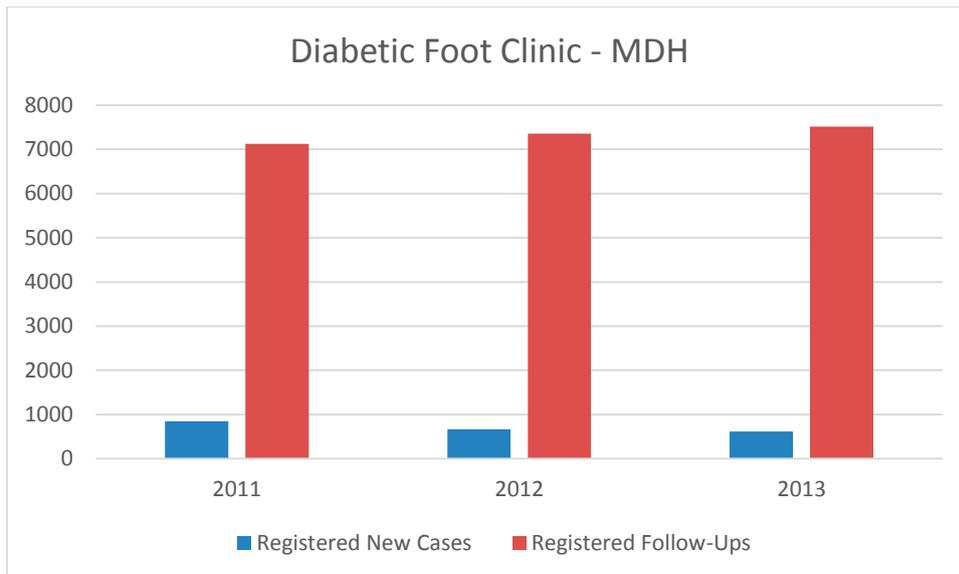


FIGURE 18: NUMBER OF ATTENDANCES AT THE DIABETIC FOOT CLINIC AT MATER DEI HOSPITAL (Directorate of Health Information and Research, 2013)

Children and adolescents under the age of 16 years with diabetes are seen by a consultant paediatric endocrinologist. The number of new cases shown in Figure 20 is lower than the actual number since new cases are admitted to hospital for metabolic stabilisation, and then seen as follow-ups at the outpatient clinic.

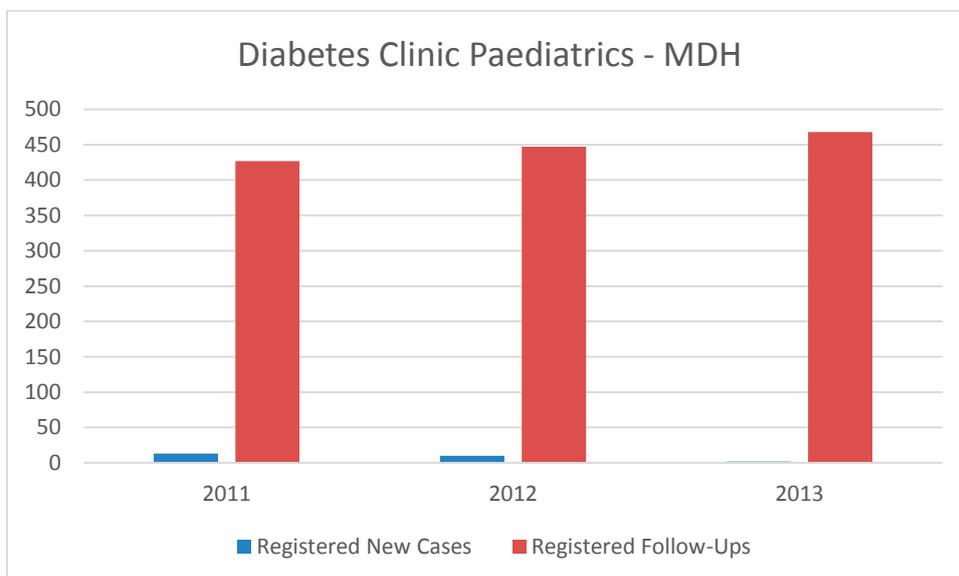


FIGURE 19: NUMBER OF ATTENDANCES AT THE PAEDIATRIC DIABETES CLINIC AT MATER DEI HOSPITAL (Directorate of Health Information and Research, 2013)

Children with T1DM who transition from paediatric to adult care experience a big change in the intensity of their follow-up. This comes at a time when they may be passing through a number of personal, physical and emotional changes. There is a need for a dedicated clinic for these to make sure there is seamless continuation of care.

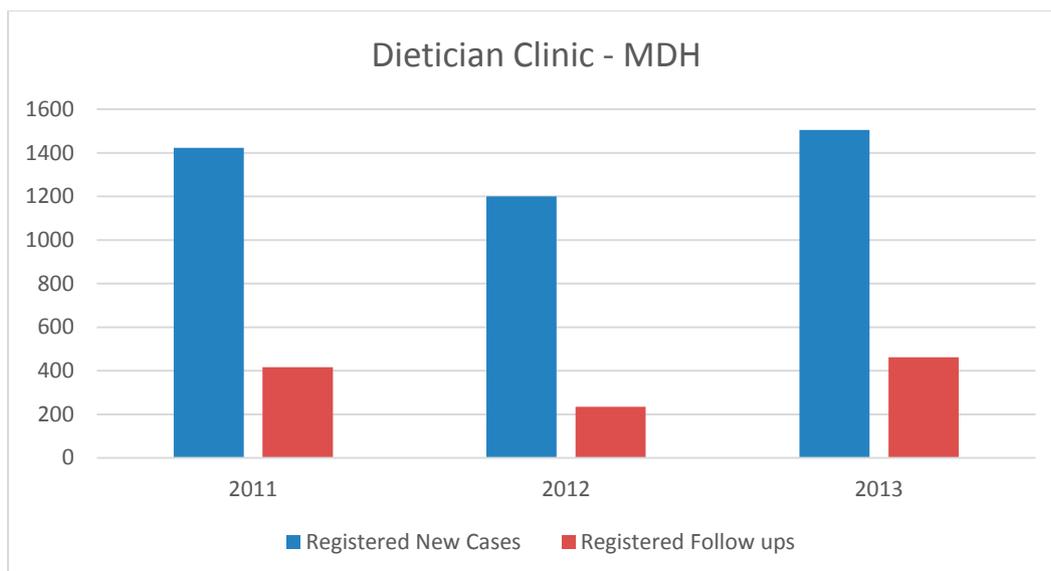


FIGURE 20: NUMBER OF ATTENDANCES AT THE DIETITIAN CLINIC AT THE MATER DEI HOSPITAL (Directorate of Health Information and Research, 2013)

Nutrition management is fundamental for the prevention of T2DM and the effective management of all types of diabetes.

CURRENT QUALITY OF DIABETES CARE

In order to assess how well the system is performing at managing Diabetes, a set of indicators were calculated according to the Final report European Core Indicators in Diabetes project (EUCID) 2008 (DG Health and Consumer Protection, 2008).

METHODOLOGY AND SOURCES

A database of persons currently receiving free treatment for diabetes was created to serve as the baseline denominator for performance measurement. This was created by extracting a list of ID card numbers from the POYC database in mid-May 2014 consisting of those persons who were dispensed one or more of the items related to Diabetes. This includes all the Insulins, Oral Hypoglycaemic Agents, Glucose strips, Insulin pens and needles. This was cross-referenced with the mortality register to exclude all persons who have since passed away. This yielded a list of 25,721 persons.

RESULTS

All the indicators use the above-mentioned 25,721 persons as the denominator, and have been calculated by cross-referencing with data from MDH Laboratory Information Service for laboratory values. The mid-year population of 2012 (National Statistics Office, 2012) was used to calculate national prevalence.

| Age group | <15 | 15-24 | 25-34 | 35-44 | 45-54 | 55-64 | 65-74 | 75-84 | >85 |
|------------|------|-------|-------|-------|-------|-------|-------|-------|-----|
| Proportion | 0.2% | 0.4% | 0.6% | 1.5% | 4.4% | 11% | 21% | 23% | 18% |

FIGURE 21: TABLE SHOWING THE PROPORTION OF PERSONS WITH DIABETES IN MALTA BY 10-YEAR AGE-GROUPS (PHARMACY OF YOUR CHOICE, 2014)

The above table shows the epidemiological profile of persons registered on the POYC database as taking one or more medications related to Diabetes. This means that about one-fifth to one-fourth of the Maltese aged above 65 are taking medications for diabetes. The true prevalence is probably even higher if one had to account for all those who are undiagnosed, or not captured in this survey since they are not on the POYC database. In fact, the pilot Health Examination Survey carried out in 2010 had indicated that the likely prevalence in the adult population is around 9%.

| Age group | <15 | 15-24 | 25-34 | 35-44 | 45-54 | 55-64 | 65-74 | 75-84 | >85 |
|------------|------|-------|-------|-------|-------|-------|-------|-------|-----|
| Proportion | 0.5% | 0.4% | 0.8% | 2.4% | 7.0% | 16% | 26% | 27% | 21% |

FIGURE 22: TABLE SHOWING THE PROPORTION OF PEOPLE IN MALTA WHO HAVE IMPAIRED FASTING GLUCOSE (FBG \geq 6.1 MMOL/L) BY 10-YEAR AGE-GROUPS (PATHOLOGY DEPT. MDH, 2014)

This table shows the distribution of Fasting Blood Glucose measurements from the hospital Laboratory Information System between April 2012 and April 2014. Population-based interventions will aim to reduce the proportion of people having raised fasting blood glucose in each age group.

| Age Groups | <15 | 15-24 | 25-34 | 35-44 | 45-54 | 55-64 | 65-74 | 75-84 | >85 |
|---------------------------------------|-----------|-------|-------|-------|-------|-------|-------|-------|-----|
| % with HbA1c tested in last 12 months | 84%* | 73% | 68% | 62% | 69% | 73% | 73% | 69% | 54% |
| Hb-A1c > 7% | 53%* * | 74% | 64% | 64% | 64% | 58% | 53% | 48% | 43% |

*The % of children tested with HbA1c in the above table refers only to venous measurements worked at the hospital lab. In reality, the % is 100% since all children get an Hb_{A1c} measurement 3-4 times per year with a Point of Care analyser.

** Glycaemic control in children is defined as HbA1c < 7.5% (not < 7% as in adults), and 53% were above this limit in 2013.

FIGURE 23: TABLE SHOWING THE PERCENTAGE OF PERSONS WITH DIABETES IN MALTA WHO HAD THEIR HbA_{1c} LEVELS TESTED IN THE LAST 12 MONTHS, AND THE PROPORTION OF WHICH WERE ABOVE 7%(Pathology Dept. MDH, 2014; Pharmacy of Your Choice, 2014)

The above table shows the proportion of persons with diabetes who have had an Hb-A1c test done within the previous 12 months. While adherence is high in children, it is at its lowest in the middle-aged and the very elderly. Hb-A1c control (defined as <7%) is at its lowest in young adults, and improves with age. This is a common phenomenon seen in other countries too (DG Health and Consumer Protection, 2008). These figures compare favourably with those of other studies (Ali et al., 2013; Chittleborough, Baldock, Phillips, &

Taylor, 2010; Donovan & McIntyre, 2010; Yong, Phillipov, & Phillips, 2007). However, our objective is to continue to improve further.

| Age groups | <15 | 15-24 | 25-34 | 35-44 | 45-54 | 55-64 | 65-74 | 75-84 | >85 |
|---|---------------|-------|-------|-------|-------|-------|-------|-------|-----|
| % with total cholesterol tested in last 12 months | Not indicated | | 62% | 64% | 69% | 74% | 75% | 70% | 52% |
| total cholesterol > 5 mmol/l | | | 37% | 40% | 40% | 32% | 30% | 28% | 31% |
| | | | | | | | | | |
| % with LDL-cholesterol tested in last 12 months | | | 62% | 63% | 68% | 74% | 75% | 70% | 52% |
| LDL > 2.6mmol/l | | | 54% | 54% | 54% | 44% | 40% | 38% | 41% |
| | | | | | | | | | |
| % with HDL-cholesterol tested in last 12 months | | | 62% | 64% | 69% | 74% | 75% | 70% | 52% |
| % of those tested with HDL < 1.25 mmol/l | | | 32% | 49% | 56% | 49% | 42% | 37% | 39% |

FIGURE 24: TABLE SHOWING THE PERCENTAGE OF PERSONS WITH DIABETES WHO HAD A LIPID PROFILE TEST WITHIN THE PREVIOUS 12 MONTHS, AND THE PROPORTION OF RESULTS WHICH WERE OUTSIDE THE RECOMMENDED RANGES (Pathology Dept. MDH, 2014; Pharmacy of Your Choice, 2014)

The above table shows similar rates as for Hb-A1c testing, with low rates of adherence in the middle-aged and the very elderly.

ADMISSIONS DUE TO COMPLICATIONS FROM DIABETES

While admissions for lower limb ulcers and gangrene are not always due to Diabetes, the vast majority of them are. Diabetic Ketoacidosis/Hyperglycaemic hyperosmolar syndrome and hypoglycaemia are three other complications that can arise from inadequate glycaemic control. A substantial proportion of other admissions (e.g. acute coronary syndrome, strokes and infections) are also related to diabetes.

| | 2010 | 2011 | 2012 | 2013 |
|-------------------|------|------|------|------|
| DKA/HHNS | 59 | 88 | 100 | 91 |
| LL Ulcer/Gangrene | 192 | 290 | 223 | 322 |
| Hypoglycaemia | 180 | 203 | 214 | 184 |

FIGURE 25: NUMBER OF DISCHARGES FROM MATER DEI HOSPITAL DUE TO COMPLICATIONS OF DIABETES PER YEAR (Clinical Performance Unit, n.d.)

LIMITATIONS OF THIS DATABASE

This is a list of all living persons (as of mid-May 2014) who were entitled to one or more of the above-mentioned items. These items are specific for people with Diabetes¹.

By cross-referencing with Mater Dei (St Luke's pre-2007) Hospital Activity Analysis over the past ten years, it has been calculated that over 21% of all persons with a discharge diagnosis of diabetes in Malta are not on this database. These are persons who are not receiving free medications/supplies either because they are not entitled to obtain them free of charge through the public health system or because they choose to buy their own medicines/supplies, or because they do not need medication (usually when metformin is contraindicated or not tolerated).

¹ With the exception of Metformin which may also be given for Polycystic Ovarian Syndrome

CHAPTER 3: PREVENTION AND EARLY DIAGNOSIS

OF TYPE 2 DIABETES

INTRODUCTION

Epidemiological studies have shown that the Maltese population has a relatively high prevalence of carbohydrate metabolism disorders in persons over 15 years. This higher prevalence is corroborated by increased rates of Maltese pregnant women with an impaired glucose metabolism. It is well established that these women are at an increased risk of development of T2DM or impaired glucose tolerance later on in life (Savona-Ventura & Savona-Ventura, 2013).

Persons are diagnosed as having diabetes according to blood glucose levels set at the threshold at which they are at an increased risk of developing microvascular, cardiovascular complications and premature mortality² (Roglic, Resnikoff, Strong, & Unwin, 2006). The situation is unfortunately not as simple as this, there is a grey area where they may be hyperglycaemic above the 'normal' ranges but below the threshold classifying diabetes³. This category of people are often termed 'pre-diabetics' and are at increased risk of developing diabetes and its complications.

The major drivers for T2DM are modifiable risk factors such as high rates of overweight and obesity in adults and children.

An integrated approach to tackling chronic diseases is the way forward. This is based on the fact that there are common risk factors and co-existence of a number of chronic diseases in a person. In Europe it was estimated that >35% of men over the age of 60 years will have two or more chronic diseases contemporaneously. An integrated, patient-centred approach to prevention will cut costs over managing the patient for each condition separately capitalising on scarce resources and having a greater impact on the individual's health (OECD, 2012).

At the same time care needs to be taken to focus on diabetes prevention on those persons deemed to be at high risk of developing this disease.

² Current WHO diagnostic criteria –fasting plasma glucose ≥ 7 mmol/L or an oral glucose tolerance test that measures venous plasma levels 2 hours after a 75g oral glucose load ≥ 11.1 mmol/L is considered diabetic

³ FBG: <6.1 mmol/L or 2-hr glucose <7.8 mmol/L

MODIFIABLE RISK FACTORS FOR DEVELOPING DIABETES

OVERWEIGHT/ OBESITY

Excess weight is widely acknowledged to independently increase the risk of developing diabetes. The magnitude of this association has been widely investigated and various strengths of association have been quoted. There is general consensus that at a body mass index (BMI) of 23kg/m² there is no additional risk of developing diabetes attributable to weight. particularly Above a BMI of 29kg/m² the risks are markedly increased whilst with a BMI of 25-29kg/m² persons were found to have twice the risk of those with a BMI of 23kg/m². Excess weight earlier on in life was also found to be associated with an increased diabetic risk (Chan, Rimm, Colditz, Stampfer, & Willett, 1994). A meta-analysis of well-powered studies of this association have found that when adjusting for the three main confounding variables (age, family history of T2DM and physical activity), the relative risk of developing diabetes was 7.28 for obese persons and 2.92 for overweight persons (Abdullah, Peeters, de Courten, & Stoelwinder, 2010). Furthermore, Wald et al. designed an algorithm to determine the percentage body weight loss that was found to neutralize one's excess diabetic risk related to weight. A 10% reduction in weight would approximately half the risk of developing diabetes whereas a 20% reduction in body weight would decrease this risk by approximately three quarters. The BMI level at which the risk for diabetes is least is 22kg/m². There is thus significant public health impact of adequate weight control at a population level as regards the diabetic risk (Wald, Bestwick, & Morris, 2012).

PHYSICAL INACTIVITY

A number of large cohort studies provide strong evidence for the value of physical activity in reducing the incidence of T2DM. Although we know that physical inactivity is an independent risk factor for diabetes, the exact values are specific to the study population. In the USA it was estimated that 13% of T2DM in men and 29% of T2DM in women was attributable to lack of physical activity whilst in Finland this ranges from 3% to 7% (Al Tunaiji, Davis, Mackey, & Khan, 2014). Although both obesity and the lack of physical activity were found to be independent risk factors for diabetes, the former was found to confer the larger risk (Rana, Li, Manson, & Hu, 2007). Physical activity in itself results in lower rates of obesity and therefore the role of physical activity in preventing diabetes should not be underestimated.

GESTATIONAL DIABETES

It is well established that women who have experienced gestational impaired carbohydrate metabolism disorders such as gestational impaired glucose tolerance and gestational diabetes (GDM) are at an increased risk of developing T2DM later on in life. A local eight

year follow up cross sectional study has shown the risk for women with GIGT/GDM was 3.6-6.7 times higher than for the general population (a G. Schranz & Savona-Ventura, 2002). Factors that were shown to increase the risk of progression to prediabetes and also to T2DM included weight gain and increased waist circumference post-partum (Huopio et al., 2014). Targeting women with elevated fasting glucose levels during pregnancy may prove to have the greatest effect for the effort required. This is a golden opportunity to target effective lifestyle interventions amongst this high risk group. One must not forget that the offspring of these women are also considered to be at an increased diabetic risk due to the altered *milieu interieur* to which they were exposed. Therefore establishing healthy attitudes will benefit both the mother and the child.

TOBACCO

Three large prospective studies suggest that smoking is associated with the development of T2DM in men and women (Kawakami, Takatsuka, Shimizu, & Ishibashi, 1997; Rimm et al., 1993) consistent with evidence linking smoking and insulin resistance. In a study on middle-aged British men, the risk of T2DM was significantly increased in cigarette smokers compared with never-smokers, despite their lower body weight. The relationship was stronger after adjustment for BMI and persisted after additional adjustment for other potential confounders (Wannamethee, Shaper, & Perry, 2001). Sufficient evidence exists to indicate that cigarette smoking is an independent and modifiable risk factor for T2DM.

HIGH BLOOD GLUCOSE (PREDIABETES)

High blood glucose is a substantial risk factor for diabetes and in the long run, heart disease and stroke. Impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) are two states of abnormal glucose metabolism that are collectively known as prediabetes. Current estimates are that up to 70% of persons with IFG/IGT may progress to diabetes (Knowler et al., 2002; Nathan et al., 2007).

In persons with diabetes, cardiovascular risk increases in a linear fashion with hyperglycaemia. The Whitehall study showed a definite graded relationship between increasing levels of hyperglycaemia above a threshold level and coronary mortality (Brunner, Shipley, Witte, Fuller, & Marmot, 2006).

METABOLIC SYNDROME

Abdominal obesity may be associated with clustering of cardiovascular and metabolic risk factors which constitute the metabolic syndrome. This includes hypertriglyceridemia, low high-density lipoprotein and cholesterol levels, high blood pressure, and elevated levels of fasting glucose. Patients with even minimal abnormalities in any 3 of the 5 risk factors for the metabolic syndrome are at heightened risk for developing CVD or diabetes. The risk for

disease increases over time as the number of metabolic syndrome characteristics accumulates and hence early management is warranted (Smith, Allwright, & O'Dowd, 2007).

EVIDENCE FOR PREVENTING THE ONSET OF DIABETES

As outlined below, there is robust evidence that in the case of diabetes, prevention does work. Evidence exists for the effectiveness and benefits of diabetes prevention, earlier diagnosis and better care of the diagnosed patient.

Numerous studies have shown how lifestyle intervention when applied consistently in the form of dietary advice and/or the introduction of sustained physical activity to a population of high risk individuals, results in the delay or actual prevention of T2DM.

One of the earliest studies in this regard is known as the Malmö study. Middle aged men with normal glucose tolerance and others who were known to have impaired glucose tolerance at baseline were assigned to continue as usual whilst others were prescribed a lifestyle intervention composed of six months' of supervised physical training and dietary treatment. This study showed a lower incidence of T2DM amongst the group who had undergone the lifestyle intervention with an increased reversal of impaired glucose tolerance to normal levels. Mortality at 12 year follow up was also found to be better for this latter group (Eriksson & Lindgärde, 1991). The Da Qing study period, in contrast, lasted for 6 years and this attempted to determine the relative effect of either a dietary intervention or an intervention involving increased physical activity on the development of diabetes. They found that diet reduced the incidence by 31%, exercise by 46% and a combination of both resulted in a reduction of 42% (Pan et al., 1997).

The Finnish Diabetes Prevention Study (DPS) was the first randomized control trial that studied the effect of lifestyle intervention of a group of obese/ overweight participants with impaired glucose tolerance at baseline. After two years of this trial, it was concluded that the intervention group had less than half the risk of developing diabetes as compared to the non-intervention group. This impact of the lifestyle change was found to persist for at least four years after the intervention was terminated. This cumulative attenuation of the individual's risk was seen with the achievement of each health promoting goal including weight loss, increased physical activity, increased dietary fibre and decreased intake of total and saturated fats (Lindström et al., 2003, 2006). The Diabetes Prevention Program (DPP) is another larger randomized clinical trial in which individuals of various ethnicities and of diverse cohorts were randomised to one of three intervention groups. One included placebo treatment, one included treatment with metformin whilst the latter was a lifestyle intervention group.

The participants of the intensive lifestyle intervention group were required to lose at least 7% of their initial body weight through a healthy diet and 150 minutes of moderate intensity physical activity per week. Individualised, targeted sessions were delivered through a carefully organized, standard curriculum. The results were clear- the group that was assigned the intensive lifestyle modification program had a 58% less risk of developing diabetes as compared to the placebo group. It is important that lifestyle interventions are patient centred rather than the one-size-fits-all approach and they must also be culturally adapted to the context within which they are to be used. Studies have shown that interventions advocating an improvement in diet alone or an increase physical activity alone or a combination of the two have been found to be equally effective.

OBJECTIVES

- Increase awareness and literacy about diabetes
- Decrease the risk of T2DM by targeting the modifiable risk factors including: overweight and obesity, physical inactivity, smoking, dyslipidaemia and hypertension, particularly in high-risk groups
- Improve the health outcomes of people with diabetes through early diagnosis, improved self-management and lifestyle modification

GUIDING PRINCIPLES

ADOPT A WHOLE OF SOCIETY AND WHOLE OF GOVERNMENT APPROACH

Diabetes is largely caused by the way we live and work. It is not caused by the health system and cannot be solved by the health system alone. Lifestyle choices are strongly influenced by trade, marketing, fiscal policies, education, transport and urban environment, media and agricultural practices. The whole of society and whole of government approach should underpin effective strategies to prevent the onset of risk factors related to diabetes and to improve the health outcomes of diabetes. This approach underpins both the Noncommunicable Disease Strategy and the Healthy Weight for Life Strategy. In order to be effective, actions resulting from the Diabetes Plan must include intersectoral action and be congruent with actions resulting from the NCD and HWL Strategies.

LIFE COURSE APPROACH

The risk causes of noncommunicable diseases including diabetes accumulate throughout life, starting from *in utero* through childhood and adolescence, adulthood into old age (Aboderin et al., 2002). The main factors at different stages of life include:

foetal life – foetal growth, maternal nutritional status and socio-economic position at birth

infancy and childhood – breastfeeding, unhealthy diet, lack of physical activity, obesity, socio-economic position

adolescence – unhealthy diet, lack of physical activity, obesity, alcohol and tobacco use

adult – known behavioural and biological risk factors

Evidence is accumulating that effective policies addressing these risks can prevent NCDs. The risk of developing diabetes is influenced by biological or social factors acting at all stages of the life course, including the exposure to gestational maternal diabetes and high birth weight. Obesity, high blood pressure and dyslipidaemia track from childhood through adolescence and young adulthood, leading to atherosclerosis and in many cases diabetes.

FOCUS ON EQUITY

Equity is the absence of avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically. Health inequity encompasses both health determinants and access to resources to maintain or improve health outcomes. The determinants of health affect people's opportunities to make and sustain healthy choices, including their ability to choose healthier diets and undertake regular physical activity, and their capability of maximising health outcomes while living with diabetes. Strategies for diabetes prevention will aim to contribute towards the reduction of health inequalities by reaching out to vulnerable and hard to reach groups.

NATIONAL STRATEGIES WORKING IN SYNERGY TO PREVENT DIABETES

Several public health strategies published over the past years focus on reducing the prevalence of risk factors relating to diabetes. Some of the actions aimed at reducing the prevalence of T2DM and its complications in the general population include the provision of education on healthier lifestyles, the promotion of healthy diets in schools and the lowering of the prevalence of excess weight especially in those with a history of first degree relatives with T2DM. The Strategy for the Prevention and Control of Non-communicable Diseases (NCD) also focuses on secondary prevention to ensure the reduction of excessive weight in persons with diabetes and lifestyle modification, to improve the level of education and self-

management in persons with diabetes and to encourage exercise among these persons. It promotes the role of primary care teams in providing primary and secondary prevention (Health Promotion and Disease Prevention Directorate, 2010).

The Food and Nutrition Policy and Action Plan (2014) identifies nutrition as a major modifiable determinant of chronic disease. This action plan takes population based approaches and individual targeted interventions through collaborative health-in-all policies and whole-of-government approach involving all levels of government and relevant stakeholders (Health Promotion and Disease Prevention Directorate, 2014b).

The Healthy Weight for Life (HWL) Strategy points out that overweight and obesity are responsible for about 80% of cases of T2DM. This strategy focuses on action related to nutrition and physical activity across the life course and within different settings. It requires a whole of government and whole of society approach in order to achieve effective actions and to reach its targets by 2020 (Superintendence of Public Health, 2012).

In addition other strategies focussing on policy strengthening the sports culture within the population, including increasing access to high quality sports facilities have also resulted in new opportunities for physical activity for different age groups in localities all over both islands (Malta Sports Council, 2006). The Healthy Eating Lifestyle Plan regulates food and drink consumed on school premises including during special activities and those provided from school tuck shops. It promotes the concept of the health promoting school by giving guidelines on both nutrition and physical activity and encouraging the integration of the school as a health resource within the wider community (Ministry for Education and Employment, 2014).

The Breastfeeding Policy builds on previous work done to make breastfeeding the cultural norm, by involving the whole family, health professionals, employers, educators and retailers to encourage exclusive breastfeeding till six months and as long as both mother and child wish to continue thereafter.

ACTIONS

INCREASE AWARENESS AND LITERACY ABOUT DIABETES

This objective needs to be tackled at various levels. Results from a recent survey on health literacy in the general population indicate that there is a need to implement a programme to improve health literacy particularly amongst certain population groups. Awareness and health literacy about diabetes should be implemented at population level, amongst individuals who are known to be at higher risk of developing T2DM, amongst individual who are newly diagnosed with diabetes and amongst health care professionals. These

programmes will be undertaken in partnership with professional associations and with NGOs through the following actions.

- Implementation of an integrated social marketing programme which provides strong messages about the risks, seriousness and impact of T2DM and focuses on the preventability of the condition. Development and implementation of a specific health literacy programme for persons with diabetes
- Provision of education and support for staff in schools in identifying and dealing with diabetes emergencies
- Design and delivery of an interactive IT based continuing professional development programme on prevention and management of diabetes for all health care workers tailored to their specific needs and levels of education

INTERVENTIONS FOR INDIVIDUALS AT HIGH RISK OF TYPE 2 DIABETES BY TARGETING MODIFIABLE RISK FACTORS

Besides the work carried out at population level, certain groups are known to have an increased risk of developing T2DM. One easily identifiable group deserving close monitoring and support is women who develop gestational diabetes. Therefore, it is foreseen that specific outreach support programmes will be developed for these women at higher risk. Other persons deemed at risk will be referred for lifestyle modification support programmes offered through the Directorate for Health Promotion. The following actions will be implemented.

- Development of formalized post-partum follow-up and prevention programmes for women with gestational diabetes
- Referral of persons deemed at high-risk of developing T2DM for smoking cessation or weight management programmes as appropriate

IMPROVE THE HEALTH OUTCOMES OF PERSONS WITH TYPE 2 DIABETES THROUGH EARLY DIAGNOSIS, IMPROVED SELF-MANAGEMENT AND LIFESTYLE MODIFICATION

Diabetes is often asymptomatic in its early stages. Yet appropriate management and glycaemic control at the outset serve to postpone complications and improve quality of life. Besides the obvious benefits of avoiding or postponing complications for the affected individuals and their families, several studies have shown economic and societal benefit through the implementation of programmes which promote early diagnosis. Earlier diagnosis consists of identifying high risk individuals and offering them appropriate diagnostic tests. The best consensus appears to indicate that whilst population based screening is not justified in terms of numbers needed to screen, there is value in implementing clinical opportunistic screening for the condition. Studies tend to agree that

screening should be targeted towards high-risk individuals. The most consistent factors that predict the likelihood of diabetes are the following and persons with any of the following characteristics should be screened using fasting venous blood glucose as the screening test for IGR and T2DM.

- Obesity (BMI >30 kg/m²)
- Family history (first degree relative)
- Raised blood pressure (Systolic >130 mmHg) and /or heart disease
- Previous occurrence of diabetes in pregnancy
- Use of drugs that predispose a patient to T2DM, including: nicotinic acid; glucocorticoids; thyroid hormone; beta-adrenergic antagonists; thiazides; phenytoin; pentamidine; anti-psychotic agents; interferon-alpha therapy.

All health care professionals who encounter persons who have at least one of these risk factors are encouraged to ask about screening for diabetes in the past 12 months and to refer persons for opportunistic screening.

Improving health literacy for people with diabetes will focus on improving their knowledge, skills and confidence, enabling them to take increasing control of their own condition and integrate effective self-management into their daily lives. High-quality structured and sustained educational programmes can have a beneficial effect on health outcomes and can significantly improve quality of life.

Successful outcomes in diabetes depend to a great extent on the role patients play in managing their condition on a daily basis. At the initial stages of diagnosis, it is fairly common for patients to pass through the recognised stages of grief for the “loss of health”. At the same time during this initial stage patients have to learn about their condition, lifestyle changes, medicines, self-monitoring, management and avoidance of complications. It is the duty of every health care professional seeing diabetic patients including doctors, nurses, pharmacists, podiatrists, dietitians to provide patients education and counselling during clinical encounters. Furthermore structured patient education, particularly at the time of diagnosis or treatment transition, is also needed. Education needs to be reinforced at regular intervals.

The current programme is primarily administered by diabetes specialist nurses. However it is recognised that further efforts need to be carried out to tailor education on self-management according to the person’s level of health literacy. Low levels of uptake of the programme have been identified and, therefore, use of modern communications media should be considered as an alternative to ensure the delivery of the key messages as well as specific outreach. The education programme should be delivered by all members of the multidisciplinary team covering different topics.

The provision of education should be based on adult learning principles that promote active learning – ideally provided within a group format, unless this is considered inappropriate. Structured programmes should be provided by appropriately trained multidisciplinary teams including, as a minimum, a dietitian and a diabetes specialist nurse (or practice nurse experienced in diabetes) who understand the principles of patient education. This is complementary to one-to-one patient education undertaken by health care professionals attending to patients with diabetes; doctors are particularly encouraged to ensure that their patients are appropriately literate about their diabetes during clinical encounters.

DIETARY CARE PLANNING AND DIABETES

Nutrition management is fundamental for the prevention of T2DM and the effective management of all types of diabetes. Newly diagnosed diabetics should be provided with a tailored and individualised dietary care plan based on the latest evidence of effectiveness.

People taking hypoglycaemic drugs and insulin will need further advice on dietary management to balance their food intake and physical activity levels with their medication. Dietary changes need to be agreed at a pace suited to the individual – regular follow up appointments are recommended in the initial stages after diagnosis or at times of transition, such as when medication is changed. People with diabetes who present with possible eating disorders (e.g. bingeing etc.) should be referred to a clinical psychologist and dietitian for a joint programme of care.

Patients need regular updating and it has been shown that when patients accept their condition they are more receptive to educational interventions.

It is, therefore, important that all patients with T2DM as well as those with T1DM receive regular educational sessions on diabetes management and control through the course of their disease. Such sessions also serve as an opportunity for patients to ask for advice and to identify persons who may require additional support from dietetic or psychological services.

Educational material will be prepared using different media to reinforce the importance of self-management for persons with diabetes.

Lifestyle modification should become standard management for all newly diagnosed persons with Type 2 Diabetes. Self-management will focus specifically on smoking cessation, weight management, optimal glycaemic control, control of hypertension, dyslipidaemia and regular screening for heart, eye, kidney and foot complications (Health Promotion and Disease Prevention Directorate, 2010).

Therefore the following actions are foreseen:

- Implementation of a clinical opportunistic screening programme to decrease the rate of undiagnosed diabetes in partnership with GPs, outpatient clinics, pharmacies, dental clinics
- Referral of newly diagnosed persons with diabetes to smoking cessation and weight management programmes
- Health literacy sessions for persons with Type 2 Diabetes specifically focussed on self-management

CHAPTER 4: IMPROVING ACCESS TO INNOVATIVE QUALITY TREATMENT

INTRODUCTION - DEFINING ACCESS TO MEDICINES AND DEVICES FOR DIABETES

The cost of ensuring access to diabetes medicines and devices should be considered as an investment by all of society to alleviate the human and financial burden of poorly controlled diabetes and its complications. The social and indirect costs (such as the loss of productivity due to illness) of diabetes-related complications may be even greater than their direct cost to health systems (International Diabetes Federation Europe, 2011). Government through this strategy is determined to make access to diabetes care be seen as an investment to promote a healthier and more productive society and is a contributor to long-term economic growth. However ensuring access to diabetes treatment is a costly, complex and resource-consuming challenge. It is nonetheless acknowledged that through the needs assessment and consultation process a general consensus emerged that this aspect of diabetes care in Malta is an important priority to be urgently addressed even though it must not be forgotten that this is also only one element in high-quality comprehensive diabetes care (International Diabetes Federation Europe, 2011).

In addressing the goal of improving access to innovative quality treatment, the strategy sets out the following objective:

- To implement a plan of expansion of the Government formulary for diabetes in order to provide access to those innovative treatments which have been shown to improve health outcomes and quality of life in persons with diabetes whilst giving due

attention to the impact of such expansion on the overall financial sustainability of our health system

- To improve access to devices that promote self-monitoring and self-management of diabetes in order to encourage patient participation in the management of their condition and foster an outcome oriented and preventive culture

GUIDELINES FOR THE TREATMENT OF DIABETES MELLITUS

TYPE 1 DM

T1DM is characterised by a complete deficiency of insulin production. Without a regular and reliable supply of insulin, people with T1DM will not survive (International Diabetes Federation Europe, 2011). An intensified insulin regimen is required in these patients consisting of both basal and prandial insulin.

Insulins may be divided into the following classes (BMJ GROUP AND THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN, 2013):

- *Conventional human insulins:*
 - Intermediate-acting (basal) e.g. isophane insulin
 - Short-acting (prandial) e.g. soluble insulin
- *Insulin analogues:*
 - Long-acting (basal) e.g. degludec, detemir and glargine
 - Rapid-acting (prandial) e.g. aspart, glulisine and lispro.

Both conventional human insulins and insulin analogues may be used in patients with T1DM (BMJ GROUP AND THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN, 2013). The long-acting insulin analogues are recommended in patients with severe or nocturnal hypoglycaemia and who are using an intensified insulin regimen (Scottish Intercollegiate Guidelines Network (SIGN), 2010). The insulin regimen should be tailored to the individual patient to achieve the best possible glycaemic control without disabling hypoglycaemia.

TYPE 2 DIABETES

T2DM occurs due to reduced secretion of insulin, or peripheral resistance to the action of insulin (insulin resistance), or due to a combination of both. Depending on the status of the condition, T2DM can be treated with lifestyle changes and/or oral and non-insulin injectable drugs and/or insulin therapy.

The treatment pathways for patients with T2DM differ amongst different international guidelines (AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS (AACE), 2013; Inzucchi et al., n.d.; National Institute for Health and Care Excellence (NICE), 2009; Scottish Intercollegiate Guidelines Network (SIGN), 2010). However, the following principles are common amongst these guidelines.

Lifestyle modification with emphasis on diet, exercise and continued education is a key pillar in the management of T2DM in any of the clinical pathways that may be pursued.

T2DM is a chronic progressive disease – requirement for multiple medications to achieve targets increases with time due to decreasing beta-cell function in the pancreas. Thus most patients will require combinations of drugs in order to lower blood glucose levels.

The HbA_{1c} target should be individualised according to several patient factors including age, co-morbid conditions, diabetes duration, risk of hypoglycaemia, patient motivation, adherence and life expectancy.

The choice of therapy should also be individualised and a patient-centred approach should be employed. Choice is determined on numerous factors including patient characteristics, profiles of the medications themselves and availability/affordability of the different options.

Patient factors that influence the choice of drugs include other co-morbidities e.g. kidney, liver and heart disease; ease of use and patient preference. Drug factors that influence the choice of therapy include contra-indications and side-effects of the drugs themselves. Particular consideration is given to the hypoglycaemia and weight gain potential of these drugs. These two side-effects can adversely affect patient safety, adherence and cost.

Metformin remains the first-line drug in T2DM if there are no contra-indications to it. Deployment of metformin at population level is a commonly used indicator of appropriate health system performance in relation to diabetes. Available data indicates that we have a fairly good rate of deployment of metformin in Malta, yet the place of metformin as the first line drug for T2DM needs to be continually emphasised.

The choice of the second-line drug following metformin is not very well backed up by studies and long term data. Thus various combinations using one or two additional oral or injectable agents are reasonable and recommended interchangeably. The aim is to achieve the patient's target level of glycaemic control without significant side-effects.

Many patients with T2DM may ultimately require insulin therapy (alone or in combination with other drugs) as the disease progresses.

The management of hyperglycaemia should be put in the context of the overall management of the cardiovascular risk of the patient. Management of hypertension and hyperlipidaemia

is a key component of successful diabetes care programmes (and ensuring successful outcomes).

CURRENT LOCAL AVAILABILITY OF ANTI-DIABETES DRUGS ON THE MALTA GOVERNMENT FORMULARY LIST

INSULINS

Entitlement to free medication through the public health sector outside a hospital setting is based on the principle of social solidarity and occurs through a system based on criteria linked to disease or means by virtue of the Social Security Act Cap 318 Article 23 and the amendment of this act - Act No. 1 of 2012 and the **Fifth Schedule** of the same Act. Those patients suffering from chronic conditions usually fall under **Schedule V** (Yellow Card), whilst those with limited means generally pertain to the **Schedule II** (Pink Card).

Human insulins - soluble insulin, isophane insulin and biphasic insulin

They are all available in vial form (for use with an insulin syringe) and cartridge form (for use with an insulin pen). The human insulins in vial form can be used in all types of diabetes without restriction. However, human insulins in cartridge form are protocol-regulated. They are only available to patients with T1DM or to those who suffer from T2DM and have accompanying visual disturbance.

Insulin glargine and insulin aspart – analogues approved for patients with type 1 diabetes only

The current entitlement protocol for glargine states that patients should have been for at least six months on a multi dose regimen of conventional insulin; they should be testing their blood sugar on a four times a day basis for at least three months; and that their blood glucose monitoring reveals frequent fluctuations in blood sugar with a minimum average of two nocturnal hypoglycaemic episodes per week.

The current entitlement protocol for aspart states that patients should have been for at least 6 months on a multi-dose regimen of conventional insulin; must be testing their blood sugar on a four times a day basis for at least three months; and that the blood glucose monitoring reveals frequent fluctuations in blood sugar with a minimum average of two postprandial hyperglycaemic episodes per week.

ORAL AGENTS AND NON-INSULIN INJECTABLES

Until recently there were only three oral agents on the Malta GFL – metformin, glibenclamide and gliclazide. These drugs are issued to patients via the Schedule V or Schedule II entitlement system. The situation has changed with the adoption of a new pathway for the treatment of diabetes as outlined in the subsequent sections in this chapter.

There are currently no non-insulin injectables on the Malta GFL.

ACTIONS

EXPANSION OF THE GOVERNMENT FORMULARY FOR DIABETES

Following the launch of the consultation document in November 2014, it was immediately apparent that the lacunae in the Government formulary for diabetes had to be addressed with urgency. For a large number of years, the hypoglycaemic drugs available on the Government Formulary remained unchanged. Conscious of the importance of strict glycaemic control, this strategy document recommends that new second line drugs are introduced on the Government Formulary List (GFL). Specifically, Repaglinide and Gliptins need to be introduced on the GFL at an early stage. It is recommended that insulin analogues – at the moment protocol regulated for T1DM - are introduced for all types of diabetes at a later stage.

Difficulties with access to treatment has been highlighted as an issue which often causes delays in starting treatment. This has been particularly highlighted for example for the use of antibiotics with serious foot infections. Steps are being taken to streamline the procedures to obtain antibiotics to treat infections without undue delay.

The following actions are therefore being implemented:

- Early provision of gliptins and repaglinide to all those who meet the clinical criteria according to an approved treatment pathway
- Reduction in bureaucracy in the current entitlement protocols for insulin analogues so that they can be given to patients with Type 1 DM upon diagnosis according to clinical advice.
- Swift access to antibiotics for infections associated with diabetes

HYPODERMIC EQUIPMENT FOR INSULIN ADMINISTRATION

There is currently a quota for the amount of insulin syringes given to patients free of charge. Pink card holders get 10 syringes per month whereas patients who have a yellow card for diabetes are entitled to 30 syringes per month. A phased process to increase the monthly quota of syringes in order to support a single use policy will be implemented starting by increasing the monthly quota of syringes for persons with Type 1 diabetes

MONITORING DEVICES FOR DIABETES MELLITUS

Persons with Type 1 diabetes usually require intensive monitoring of their blood sugar. The current entitlement criteria for the supply of blood glucose monitoring strips for persons with Type 1 diabetes are age-dependent. In order to promote self-management of diabetes, it is recommended that four blood glucose strips daily are given to all patients with Type 1 diabetes.

CHAPTER 5: FURTHER DEVELOPING PATIENT CENTRED SERVICES IN DIABETES CARE

PURPOSE

The management and care of persons with diabetes in Malta has developed over the years in line with the St Vincent Declaration. The hub for specialist care and management of diabetes and its complications is the Diabetes Clinic at Mater Dei Hospital. Over the past years, efforts have been made to develop a shared care programme with primary care through the health centres. Both the care given at Mater Dei and health centres is supported by nurses and allied health professionals. Private general practitioners and specialists in private practice also play an important role in the care and follow up of persons with diabetes. Whilst recognising the efforts made by dedicated health care professionals to provide quality services for persons with diabetes, there always remains more that can be done to ensure that access to high quality services for all patients irrespective of where they obtain their care. The strategy proposes the implementation of a number of initiatives to facilitate the implementation of a *coordinated, integrated, multidisciplinary service of consistently high quality for all persons with diabetes.*

The main focus of future service development is to ensure that all persons with diabetes are monitored regularly to ensure risk factor modification and management, including good glycaemic control, to avoid complications. Persons with uncomplicated T2DM should be cared for primarily in a community setting through shared care between trained general practitioners and diabetes specialists. This will allow the diabetes clinic based at Mater Dei Hospital to dedicate its resources towards the fulfilment of its mission as a tertiary referral centre for all patients with diabetes identified as requiring regular and intensive specialist care provision whilst remaining the hub for the coordination of all diabetes related services. However the need to provide high quality services for persons with diabetes in hospitals other than Mater Dei emerged as an important and urgent priority during the consultation process which needs to be addressed.

The development and elaboration of detailed care pathways for patients with different needs has been identified as a key component for the successful implementation of consistently high quality care across hospital and community and between public and private sectors. Care pathways are a means of ensuring consistently high quality of care for all patients as well as educating and empowering patients to engage as partners in their own care. The shared care programme for patients with uncomplicated T2DM has been recently updated. One important addition has been the possibility for private sector practitioners to participate in this programme. This is an important component that needs to be fully

implemented to ensure that persons seen in the private sector have access to further follow on care without encountering difficulties.

The provision of access to key diabetes related services for all doctors participating in the approved shared care program will be implemented in a phased manner.

AN INTEGRATED SERVICE OF HIGH QUALITY

Diabetes is known to be associated with increased risk of long-term complications. These include microvascular disease, such as retinopathy, neuropathy and diabetic nephropathy. There is also increased risk of developing macrovascular disease (coronary heart disease, peripheral vascular disease and cerebrovascular disease).

Health care services for persons with diabetes have the aim of preventing complications as well as ensuring holistic support and well-being. There is a good infrastructure that has been developed over the years particularly the shared care programme between the diabetes clinics in health centres and the specialist referral centre in Mater Dei Hospital which provides a starting point on which to continue to build.

The main challenge ahead is to move from a system of passive surveillance to a system where all persons with diabetes are actively invited for monitoring of preventable complications. Another important aspect is the strengthening of the human resources complement to ensure that persons deemed to be at greater risk or who are in need of additional support are able to obtain the necessary care and assistance promptly with regular in-depth support.

PHILOSOPHY OF CARE

Persons with diabetes need the care and support of a multidisciplinary team of professionals.

T2DM is a common chronic condition whose prevalence is set to increase particularly in view of demographic trends. The philosophy of care being recommended is that of management in the community based upon continuity, active follow up, quality documentation and rapid links to specialist advice and care.

MANAGEMENT OF GESTATIONAL DIABETES

Diabetes in pregnancy can have serious consequences for both mother and baby if undiagnosed and untreated. Systematic screening for diabetes in all pregnant mothers will continue to be undertaken. A national standard of care for screening, management of the condition in pregnancy and follow up after pregnancy will be developed to ensure that all pregnant mothers get the best possible care. Documentation on the screening tests performed and their outcomes will be maintained by all antenatal care centres. Mothers who develop gestational diabetes will be followed up in an active and enhanced manner after delivery since they are known to be at higher risk of developing T2DM.

TYPE 2 DIABETES - SHARED CARE BASED ON CONSISTENCY, QUALITY AND CONTINUITY

The needs of persons with T2DM will vary depending upon their age, disease progression and existence of other comorbidities. This may require the tailoring of individualised care. However, there are key common principles that apply to all persons with T2DM in our efforts to avoid or delay the emergence of complications.

Consistency, comprehensiveness and active surveillance shall be the hallmarks of the diabetes care programme. In order to fulfil these objectives, the department of primary care and the diabetes centre at Mater Dei Hospital have updated their shared care programme. Although a minimum national standard of care is prescribed, patients are also free to choose where and how they wish to receive care for their diabetes. The aim is to create a system that integrates care provision between hospital and the community and between the public and private sectors.

DIAGNOSIS AND EARLY STAGES OF TYPE 2 DIABETES

The diagnosis of T2DM is often a chance finding arising from a routine health check carried out through one's family doctor or health centre. Persons diagnosed with T2DM should receive the best support and care possible immediately upon a confirmed diagnosis. All persons with newly diagnosed T2DM will be invited and encouraged to enrol in the national diabetes prevention and management system. This enrolment can be performed through the health centres.

In line with this proposal all newly diagnosed patients by public or private general practitioners are to be referred to the health centres where the nurses in charge of managing

the diabetes clinics ensure that the patient is enrolled in the national diabetes information system.

Appointments are made for specialist assessment and review by a diabetologist as well as initial screening for diabetic retinopathy and podiatry review. Baseline investigations and measurements are taken and recorded. Patients will be referred for health literacy and diabetes education sessions. Patients will also be referred for smoking cessation, weight management or exercise assessment and prescription as may be required.

Both public and private general practitioners shall retain the right to refer patients directly to the Mater Dei diabetes clinic, if this is clinically indicated to do so.

The choice to access treatment in the private sector at all stages remains with the patients who can indicate the name of the private family doctor of their own choice who will continue to provide routine follow up or that of a private diabetologist.

All patients irrespective of whether they choose to have their care in a public or private setting will be invited to participate in the national diabetes programme. In the shared care programme all persons with T2DM diabetes are invited to enrol in a national screening programme for prevention of complications. Through such enrolment, patients shall be invited at pre-established intervals for preventive screening encounters. This will guarantee that all persons with diabetes have annual blood tests to ensure good glycaemic control, monitor renal function and blood lipids. These results are recorded in the system and provided to the patient's general practitioner. This will avoid duplication of tests. The system will ensure that examinations or tests carried out in the private sector are not repeated unnecessarily in the public sector. Through this programme patients shall be invited to undergo regular screening through clinical examination, blood investigations, eye screening and foot screening as outlined in the shared care programme. In this manner it is ensured that all persons with diabetes benefit from a national standard of care. The importance of screening for complications will also be addressed in the educational campaigns.

Active follow up and surveillance will be offered particularly to persons who do not appear to be attending for structured follow up. An enhanced focus on social issues that may deter persons from seeking appropriate care for their diabetes will be made.

All patients enrolled in the shared care programme still retain the right to be seen by a specialist for their diabetes care. Besides the scheduled routine follow ups at the prescribed time interval appropriate for their clinical condition, urgent fast track referrals from both private and public GPs participating in the shared care programme will be facilitated to ensure prompt access for patients who need to be given urgent specialist attention.

The Pharmacy of Your Choice Scheme will continue to play an important role in the care of persons with diabetes through the provision of advice pertaining to medicines and their side effects, assistance with queries regarding self-management and recognition of non-compliance or need for medication review. The pharmacist is also an integral part of the multi-disciplinary team and should take the opportunity to reinforce the need for enrolment into the diabetes information system, regular attendance for screening and for updates on matters relating to diabetes self-management.

Clinical pharmacists are in a position to collaborate with other health-care professionals and can use their expertise to manage and monitor diabetes treatment plans. They have a role in the approach to patient-centred care and can intervene on initiation, dosing, monitoring and discontinuation of drug therapy. In the hospital setting clinical pharmacists can intervene on the wards or during out-patient clinics e.g. diabetes clinic. On the wards they actively participate in medication selection as part of the medical team. They also perform medication reconciliation which is a formal process whereby pharmacists work together with patients, families and care providers to ensure that accurate and comprehensive medication information is communicated consistently across transitions of care

In the out-patient clinics clinical pharmacists can offer interim drug therapy visits, patient education, treatment adherence monitoring, health barriers assessment and prevention screening⁶. Utilization of pharmacists as an essential part of the healthcare team to prevent and manage disease in collaboration with other clinicians can improve quality, contain costs, and increase access to care.

Recognition of pharmacists as healthcare providers, clinicians and an essential part of the healthcare team is appropriate given the level of care they can provide.

ONGOING CARE AND SUPPORT

Ongoing care and support for persons with T2DM shall primarily take place in the community through the shared care approach with the involvement of both the public and private sector depending upon the patient's choice.

In order to achieve best outcomes and to make best use of resources, it is envisaged that patients with uncomplicated T2DM will be cared jointly by general practitioners trained in diabetes care and by a diabetologist. The frequency of these visits will be as clinically required, but all patients should be seen at least once annually. Patients with brittle diabetes, diabetes during pregnancy or complications shall be cared for primarily by diabetologists. At annual follow up, patients will have routine clinical review and investigations in line with the national standard for diabetes care. All results are to be captured in the diabetes information system. Appointments for eye and foot screening are

organised and appointments for specialist review are made on a routine or urgent basis depending upon clinical findings.

During follow up visits, patients are also specifically encouraged to attend follow up educational sessions and maybe referred for dietetic or psychological advice as required.

SPECIALIST INTENSIVE CARE THROUGH AN MDT APPROACH

The shared care programme based primarily in a primary care / community setting is intended for persons with uncomplicated T2DM.

Persons with T1DM, Gestational Diabetes, maturity-onset diabetes of the young (MODY), other rare forms of diabetes, early onset T2DM and T2DM with complications or which is difficult to control require management of their diabetes given within a specialist setting with regular follow up from all members of the multidisciplinary team.

Dietary and psychological consultations should be considered as part of the routine follow up for persons requiring close monitoring and support.

Documentation of all care episodes will be maintained through the diabetes information system.

Tailored educational sessions in small groups or one to one will be organised as required particularly for persons going through life transitions and for young women in relation to planning pregnancy.

PREVENTION AND MANAGEMENT OF EYE COMPLICATIONS

Diabetes increases the risk of cataracts and of damage to the retina of the eyes (diabetic retinopathy). In Europe, cataracts accounted for of 13.8-21.6% blindness in 2010, whilst diabetic retinopathy accounted for 3.7-4.2% (Bourne et al., 2013). The prevalence of blindness secondary to retinopathy has decreased in many parts of the world because of regular eye screening. In the UK, where a national diabetic retinopathy screening is in place, 56.0% of T1DM subjects have retinopathy and 11.2% have sight-threatening retinopathy; the corresponding figures for T2DM are 30.3% and 2.9% respectively (Thomas et al., 2014). The importance of such regular screening lies in the fact that diabetic retinopathy is often asymptomatic until it has caused irreversible damage and visual loss.

A number of persons with undiagnosed diabetes, unfortunately present de novo with vascular eye complications. This should be addressed through the setting up of the diabetes screening programme.

Furthermore eye complications can be treated more easily if diagnosed when the patients are still asymptomatic. The establishment of an organised eye screening programme for all persons with diabetes and prompt referral in cases where suspicious pathology is found will enable eye complications to be tackled earlier and more aggressively.

There is a need to educate persons with diabetes about the benefits of early laser therapy. The overall goal is to continue to reduce the incidence of blindness associated with diabetes.

All persons enrolled in the national diabetes information system will be assessed and monitored regularly to ensure good glycaemic control. This will already assist in the preventing microvascular disease but alone it is not enough. The situation today is such that not all persons with diabetes are carrying out appropriate and regular screening for eye complications.

As part of the educational sessions and campaigns, persons with an initial diagnosis of diabetes are made aware of the important of attending screening since Argon laser treatment works best when patients are still asymptomatic.

Screening will be performed through an annual assessment using the retinopathy screening fundus cameras that have recently been installed in health centres as well as the fundus cameras available at Mater Dei Hospital. Persons enrolled in the national diabetes information system will receive an annual invitation for screening and assessment. Fundus images taken by trained ophthalmology nurses or other trained health care professionals and reviewed by ophthalmologists or optometrists shall be assessed using standard criteria. Persons with suspicious or definitive pathology will be referred to the ophthalmic department at Mater Dei Hospital through an agreed fast track system.

PREVENTION AND MANAGEMENT OF KIDNEY COMPLICATIONS

Diabetes is the leading cause of kidney disease. Diabetic kidney disease is the medical term for kidney disease caused by diabetes. Diabetic kidney disease affects both kidneys at the same time.

Diabetic kidney disease increases mortality even at its early stages (Arun et al., 2003; Neil et al., 1993). It is now the major cause for the need of dialysis in many countries (Foley & Collins, 2009) and the proportion of dialysis patients who are diabetic continues to rise (Van Dijk et al., 2005). Although outcomes of dialysis in diabetic subjects have improved (Van Dijk et al., 2005), mortality is still quite high with a median survival of 3.84 years in T1DM and 2.16 years in T2DM (Bell et al., 2014). Dialysis is associated with significant health care costs in all patients, but costs are even higher in diabetic subjects by about 27% (Foley & Collins, 2009).

Intensive management of blood glucose or glycaemic control has shown great promise for people with diabetes, not only to prevent kidney disease but also in those in the early stages of chronic kidney disease. Regular monitoring, lifestyle changes and medication are all important to help persons with diabetes achieve good control.

Screening for diabetic kidney disease is carried out using three simple tests:

- Blood pressure test. This test must be done at every health care visit.
- Albumin and creatinine measurement. A sample of urine for a urine albumin-to-creatinine ratio test should be done at least once a year. An elevated result is a warning sign of kidney disease.
- Estimated glomerular filtration rate (eGFR) test. This blood test measures how much blood the kidneys filter each minute. A reduction in the eGFR may indicate kidney damage or kidney failure. This test is performed at least once a year.

High blood pressure is the other leading cause of kidney disease in people with diabetes. High blood pressure can also be a result of damage from kidney disease. In persons with diabetes, the presence of hypertension may mean that the kidneys are already damaged. Even a small rise in blood pressure can quickly make kidney disease worse.

Some persons will eventually require support through dialysis. Specialised care and attention will continue to be given to these patients with an emphasis on pre-dialysis counselling and preparation.

A number of persons with diabetes will unfortunately develop diabetic kidney disease. Persons who are deemed at risk of requiring renal replacement therapy should be referred to a clinic which will help educate and prepare them psychologically for this difficult transition in care.

Efforts will be made to establish a pre-dialysis clinic with education and support through a multi-disciplinary team.

Persons with diabetes requiring dialysis will receive the best support and care possible through the renal unit at Mater Dei Hospital. Recently the unit has extended its hours of service in order to continue to better meet the patients growing service needs.

PREVENTION AND MANAGEMENT OF FOOT COMPLICATIONS

Patients with T2DM mellitus were found to be nearly 400 times more likely to undergo an initial minor toe (transphalangeal) amputation and had almost a 12-fold increased risk of a below-knee amputation (Humphrey et al., 1994). More than 60% of lower-extremity amputations are believed to be attributable to T2DM (Humphrey et al., 1994). The

25-year cumulative incidence of lower-extremity amputation in people with T1DM was estimated (in the Wisconsin study) to be 10.1% (Sahakyan, Klein, Lee, Myers, & Klein, 2011). Diabetes is also associated with worse outcomes in hospitalised patients with foot problems (Nirantharakumar, Saeed, Wilson, Marshall, & Coleman, n.d.). In patients undergoing lower extremity bypass surgery, it is associated with worse outcome (Wallaert et al., 2012), longer hospital stay and higher costs (Malone et al., 2014).

There is a need for a proper national foot screening programme to become established where all persons with diabetes are offered appointments in their local health centres for podiatric foot assessment with risk stratification and follow up intervals based on that risk assessment. The programme for diabetes should constitute first level screening and second level assessment.

Patients with diabetes would benefit from an initial assessment with subsequent follow ups according to risk stratification but some patients deemed to be at higher risk will benefit from more regular and specialised assessment and follow up. This first level screening should occur at all health centres and should include a vascular, neurological and biomechanical assessment.

If vascular pathology that requires immediate intervention is confirmed, patients will be referred through a fast track system for a full vascular assessment at Mater Dei Vascular Unit. Closer attention will be given to foot biomechanics such that further service development to adopt preventive measures that can postpone the occurrence of foot complications shall take place in consultation with the professionals concerned.

Persons experiencing vascular complications should be able to access the necessary treatment without delay. This could include access to antibiotics and special dressings.

ORTHOTICS AND PROSTHESIS

Persons who undergo surgery require appropriate support and rehabilitation. One of the key sources for such care is the Orthotics and Prosthetics Unit.

Investment in upgrading of the orthotic and prosthetic facility will take place as part of the overall investment in the rehabilitation facility through a public-private partnership. Investment in training of human resources will also be addressed as a priority for the strengthening of the multi disciplinary team for diabetes.

ALLIED HEALTH

The role of allied health practitioners in the support of persons with diabetes ranges from primary prevention through education, to diagnosis in the laboratories, to provision of support at all stage of the illness. The allied health professionals play an important role in the management and improvement of care outcomes for diabetes. The main areas identified for priority investment in human resources are for dietitians, prosthetists and orthotic technicians.

GOZO

Gozitan residents who are diabetic also deserve the best standards of care and management for their condition. Although some outreach is presently performed there is a need to increase the presence of specialists on the island. Whilst Mater Dei Hospital remains the tertiary referral centre for all persons with diabetes in the Maltese islands, it is also important that for uncomplicated T2DM, Gozo also joins the shared care programme as this will allow routine follow up to be carried out to the same standard as being advocated for patients in Malta. *The setting up of a specialist diabetes service in Gozo* is a key priority in this strategy which will be achieved with the development of the Gozo Health Hub through a Public Private Partnership.

MENTAL HEALTH SERVICES

Diabetic patients with mental health problems will benefit from the envisioned improvements in the mental health sector.

ELDERLY PERSONS WITH MULTI MORBIDITY

Diabetes affects more than one in four persons over the age of 60 in Malta. The management of diabetes in the elderly must be carried out in the background context of other conditions. Care plans must be carefully developed where the treatment of hyperglycaemia should not be carried out in isolation but should be balanced with the risks of hypoglycaemia, falls fractures etc. The provision of drugs which have a low hypoglycaemia risk is also important in this regard and is an important priority that is already being addressed.

Specialised outreach clinics will be implemented in geriatric settings with improvement of the quality of care for elderly persons with diabetes

Elderly persons who are home bound and in need of support for insulin administration should be provided with simple regimes that are easy to administer and that can facilitate self-care and adherence.

DIABETES INFORMATION SYSTEM

The capture of data on all patients with diabetes at a national level in a single information system allows active surveillance through personalised invitations for screening in order to encourage a high attendance. It will also allow measurement of progress in attaining the set targets of the strategy, regular evaluation and benchmarking with other health care systems. Therefore every effort should be made to ensure the capture of data for all persons with diabetes in the information management system. This will require training and rolling out of access. It will be important to ensure that the data available in this system would be eventually integrated in the electronic medical record once this is developed at national health system level.

Initially, it is proposed that investment is made in a call/recall system that can allow patients to receive reminders to attend appointments, have blood investigation and access retinal and foot screening programmes. This system will be invaluable in identifying persons who are not being followed up and instituting active surveillance and outreach.

As a result of these initiatives the following actions will be implemented:

- *A high quality electronic health record for all patients with diabetes as part of the national health ICT infrastructure*
- *The setting up of a call and recall system for setting appointments for eye and foot screening*

CHOICE

Freedom to choose one's health care provider will remain an important principle since the doctor-patient relationship is key to a successful outcome in the management of diabetes. Whilst patients will be offered the opportunity to access good quality health care offered free of charge through the diabetes clinics in health centres, it is recognised that some patients will prefer to remain under the care of their own private general practitioner or private specialist. It is nonetheless strongly recommended that all patients be encouraged to enrol in the national diabetes information system in order to access the opportunity for structured monitoring and screening on a regular basis.

Family doctors will have full access to individual patient's data on the Diabetes Information System with the patient's consent.

CHAPTER 6: QUALITY OF LIFE: THE PATIENT PERSPECTIVE

In keeping with the WHO definition of health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”, the care for persons with diabetes needs to encompass not only the biological aspects of the disease, but psychosocial aspects too. The goal is to empower persons with diabetes by increasing their levels of self-efficacy and self-care.

DIETETIC SERVICES

Dietary guidelines should be addressed immediately at diagnosis in order to introduce a healthy diet early on, especially when weight loss is required in obese persons.

An increase in the complement of trained dieticians which is possible due to the implementation of local degree programmes and practical training in partnership between the University of Malta and the Ministry for Energy and Health will enable a quality leap in the dietetic services that can be offered.

The use of personalised mobile technology (mhealth) can direct patients towards self-regulation in the choice of a healthy diet.

Persons with diabetes and their families also require access to routine visits offered by psychologists. Such a service is particularly important for parents with children who are diagnosed with diabetes, the children themselves, adolescents, young adults and persons of all ages going through life transitions. Some of these have no-one to turn to to express their innermost struggle and difficulties. Couples have encountered marital problems when their child becomes diagnosed with diabetes, older patients have had to deal with anger, frustration, denial, depression and rebellion all on their own, sometimes leading them to become anti-social and unresponsive to their own wellbeing. Children and adolescents have to tackle bullying, denial of their condition so that they do not stand out as different from their friends, leading some to stop taking their insulin resorting to drugs and hiding their condition even from their most intimate friends and partners.

Furthermore the Health Interview Survey conducted in the Maltese islands in 2008 showed that persons with diabetes have a higher prevalence of anxiety and depression. Depression can affect the individual's motivation to comply with diet and treatment leading to complications and further contributing to stress and anxiety. All health care professionals

involved in the care of persons with diabetes should be trained to recognise the signs and symptoms of anxiety and depression.

DIABETES HELPLINE

Persons with diabetes, particularly those who are dependent on insulin will often encounter a crisis or a new situation which they feel ill-equipped to deal with. Besides scheduled support for dietary and psychological advice, persons with diabetes know that the timely response to queries arising on a day to day basis is invaluable. In such circumstances, timely advice given over the phone may avert a visit, an admission or trigger the need for an urgent consultation. At present, an informal arrangement on a voluntary basis has been in place. Given the burden on the providers of the service and the growing numbers of patients / relatives who could benefit from such a service, it is felt that a more formal arrangement ought to be established.

A formal 24/7 nursing led support service will be established once sufficient trained human resources to staff the service are available. This would help persons who need quick advice over the phone.

DIABETES LITERACY

Patient Diabetes Education (PDE) has been shown to improve outcome indicators and ultimately the quality of life of persons with diabetes. They are effective by improving diabetes knowledge, lifestyle and psychosocial outcomes. Holding these sessions in the community would be more accessible, and reduce the stigma associated with hospital-based care.

Education should be an integral part of the management of all people with diabetes: from around the time of diagnosis, on an ongoing basis, based on annual assessment of need, and on request. A trained multidisciplinary team can provide education to groups of people with diabetes, or individually if group work is considered unsuitable. Where possible, family members or friends should be included. These should be led by health-care professional with specialist training in diabetes and delivery of education for people with diabetes. It should be accessible to all people with diabetes, taking account of culture, ethnicity, psychosocial, and disability issues. Education can be delivered in the community, and in different languages. Techniques of active learning should be used, adapted to personal choices and learning styles. The use of modern communications technologies may advance the methods of delivery of diabetes education (Cilia, 2007).

Government will support the Malta Diabetes Association to develop a diabetes literacy programme in the community in keeping with its overall commitment to work in partnership with relevant NGOs to address this important condition in Malta.

WORK/EMPLOYMENT

Persons living with diabetes do not only have rights but also duties and this is not always highlighted. It is important to instil in the person with diabetes that they should not hide their condition. The person with diabetes has to make their condition known to their immediate friends and colleagues at work. They should be informed on the symptoms of hypoglycaemia and how to remedy it in cases of emergency. The employer on their part can take the necessary steps to ensure employee wellbeing by ensuring that the employee is not hindered in taking the necessary measures to control their diabetes, such as by providing a private space where they can monitor and inject.

Educating the general public on diabetes and removing the taboo attached to this condition would also address discrimination when it comes to job interviews. Persons with diabetes can and do live normal everyday lives if they are well-controlled. Prospective employers should not be wary of employing persons with diabetes especially if they are provided with proof that the person is well controlled.

Whatever the circumstances, it is important to carry identification on the medical condition. The Maltese Diabetes Association distributes, free of charge, Identification ID stating that the holder is a person with Diabetes. This would help prevent instances where someone with hypoglycaemia is mistaken to be under the influence of mood-altering substances. Initial first aid would also be more effective if those who assist or paramedics know that the person has diabetes. In addition, the Department of Diabetes and Endocrinology and the Diabetes Education Unit also give out identification cards with patients' details, emergency contact details and current treatment and dose written on the card.

SOCIAL SUPPORT

Persons experiencing personal or social difficulties in their life may also find it difficult to cope with their diabetes. Persons who are socially excluded also need to be actively supported through the efforts of psychologists and social workers since failure to address their social problems will not allow for the attainment of successful outcomes in the management of their diabetes.

In families and persons at-risk of poverty and low income families, clinician recommendations might be completely disregarded due to the lack of resources. Such circumstances are especially evident in families with small children and pensioners. Often these persons need a friendly ear to turn to, someone who is willing to hear them out and encourage them to keep going and not give up as well as to guide them to sources of practical support.

Quality of life deteriorates once a person with diabetes develops complications due to a changed lifestyle. The burden on the person and the immediate family cannot be quantified. They have to adjust to their new medical condition, frequent visits to their doctors and admissions to hospital.

Social support for persons with diabetes who are experiencing a difficult social situation will help these persons maintain normoglycaemic control and decrease the risk of complications.

CHAPTER 7: PAEDIATRIC DIABETES

EPIDEMIOLOGY OF CHILDHOOD DIABETES IN MALTA

T1DM is one of the commonest chronic conditions in childhood. The incidence of T1DM in Malta during the period 2006 - 2010 in children under the age of 14 years is calculated to be 21.86/100,000/year, with the highest incidence registered in the 5 - 9 year old age group (Formosa, Calleja, & Torpiano, 2012). An annual increase in incidence over this period has been registered in children under ten years. The reasons for this increase in incidence are unknown and this phenomenon has also been observed in other countries (Gale, 2002).

| Age group | Mean incidence (per 100,000 per year) | Annual increase in incidence |
|-----------|---------------------------------------|------------------------------|
| 0 - 4.9 | 21.7 | +39% per year (p = 0.04) |
| 5 - 9.9 | 30.4 | +31% per year (p = 0.026) |
| 10 - 14 | 16.1 | - 6.5% (p = 0.66) |

TABLE 1: INCIDENCE OF DIABETES IN CHILDREN 2006-2010 (SOURCE: DATABASE MAINTAINED BY PAEDIATRIC DIABETOLOGIST MATER DEI HOSPITAL AUGUST 2014)

Most children presented with classical symptoms such as increased thirst and an increase in the frequency and volume of urine.

| Mode of presentation | Proportion (%) |
|--|----------------|
| Subacute symptoms (polyuria, polydipsia) | 57.9 |
| Diabetic ketoacidosis | 41.0 |
| Asymptomatic hyperglycaemia | 1.1 |

TABLE 2: MODE OF PRESENTATION (SOURCE: DATABASE MAINTAINED BY PAEDIATRIC DIABETOLOGIST MATER DEI HOSPITAL AUGUST 2014)

PERFORMANCE AND OUTCOMES

According to ISPAD recommendations, young people with T1DM should achieve an ideal HbA1c target of < 7.5% (IFCC < 58 mmol/mol) (Rewers et al., 2009). Analysis of 2013 data showed that almost 44% of diabetic children making use of the paediatric diabetes service at Mater Dei Hospital managed to achieve this target:

| HbA1c (%) | Proportion of patients (%) |
|-----------|----------------------------|
| < 7.5 | 43.8 |
| 7.5 – 8.0 | 26.6 |
| 8.1 – 9.5 | 25 |
| > 9.5 | 4.6 |

TABLE 3: HbA1c AS AN INDICATOR OF OUTCOME (SOURCE: (FORMOSA N, TORPIANO J; UNPUBLISHED AUDIT))

The mean HbA1c by age-group was as follows:

| Age (years) | Mean HbA1c (%) |
|-------------|---------------------|
| 0 – 10.9 | 7.53 (± 0.16) |
| 11 – 16 | 7.85 (± 0.25) |

TABLE 4: MEAN HbA1c BY AGE GROUP

These results are very encouraging, especially when compared to other countries in the European Union. In England and Wales, only 17.4% of children and young people with diabetes achieved an HbA1c of < 7.5% during the period 2011 - 2012 (Royal College of Paediatrics and Child Health, 2013). In order to achieve even better results in Malta, it is necessary to make the following changes as already outlined above:

ENSURING QUALITY SERVICES FOR CHILDREN WITH DIABETES

The first diabetes clinic in a Government hospital (St Luke's Hospital) was set up in 1963. Since 1969 diabetic children were managed by Paediatricians. or by physicians specialised in adult internal medicine. In 2006, the responsibility of care of diabetic children was transferred to the Department of Paediatrics with the appointment of a Consultant Paediatric Endocrinologist. Since that time, the Paediatric Diabetes Service (PDS) has been involved in the care of 181 children with diabetes, 95% of whom had T1DM. The upper age limit within the paediatric diabetes service was initially 14 years, but this was extended to 16 years in 2011. There are currently around 140 children under the age of 16 years with diabetes (94% with T1DM) who make use of the paediatric diabetes service.

Children with new-onset T1DM and their families require intensive diabetes education by a paediatric diabetes healthcare (DHC) team to provide them with the necessary skills and knowledge to manage this disease. The complex physical, developmental and emotional needs of children and their families necessitate specialized care to ensure the best long-term outcomes. Newly-diagnosed patients are admitted to hospital for an average of 5 - 7 days for metabolic stabilisation as well as intensive education of the family regarding diabetes care. During this initial period of hospitalisation, each individual patient's family receives an intensive, structured programme of education that takes up 20 hours or more. This includes the following subjects:

| By specialist doctors | By diabetes nurse specialists | By dietitian |
|--|---|---------------------|
| Nature of diabetes Diabetes complications Ketones and their monitoring Diabetic ketoacidosis Diabetes co-morbidities Basics about carbohydrates Insulin action profiles Hypoglycaemia management Hyperglycaemia management Sick day rules | Use of glucagon Use of insulin pens Self blood glucose monitoring | Meal planning |

TABLE 5: LIST OF DIABETES EDUCATION SUBJECTS COVERED BY HEALTHCARE PROVIDERS

On average, each child is reviewed around six times a year, although newly-diagnosed patients are seen much more frequently in the first few weeks after discharge from hospital. Very young children (e.g. under 6 years of age) also require more frequent review. Relatively few patients miss outpatient appointments. In order to ensure that no children are lost to follow-up, those who miss appointments are contacted by phone and another appointment is given at the first available opportunity. A separate visiting consultant clinic is also held at Gozo General Hospital every 3 - 4 months in conjunction with the consultant paediatricians at that hospital.

The introduction of point-of-care capillary blood testing for glycosylated haemoglobin (HbA1c) in 2012 has allowed the measurement of HbA1c every 2 – 3 months on all young children with diabetes. This has been found to be very useful in the management and education of young people with diabetes.

The care and management of children and adolescents with diabetes is also focused towards preventing complications later on in life. The following table shows the recommended screening programme for children with diabetes as recommended by the International Society for Pediatric and Adolescent Diabetes (Donaghue et al., 2014):

| Complication | Start of screening | Screening methods and frequency |
|-----------------------|--|---|
| Retinopathy | From age 10 and after 2 - 5 years' diabetes duration | Annually: Direct ophthalmoscopy through dilated pupils by experienced observer, or fundal photography. |
| Nephropathy | From age 10 and after 2 - 5 years' diabetes duration | Annually: First morning urine albumin-creatinine ratio (ACR). An abnormal result should be confirmed in at least 1 of 2 subsequent urine collections. |
| Neuropathy | From age 11 and 2 years' diabetes duration | Annually: History and examination. |
| Macrovascular disease | After age 10 | Annually: Blood pressure. Every 5 years: Fasting blood lipids. |

TABLE 6: RECOMMENDED SCREENING PROGRAMME (COMPLICATIONS) FOR CHILDREN WITH DIABETES (INTERNATIONAL SOCIETY FOR PEDIATRIC AND ADOLESCENT DIABETES)

T1DM may also be associated with a number of co-morbidities. The following table shows the recommended screening for these conditions as recommended by the International Society for Pediatric and Adolescent Diabetes (Kordonouri et al., 2014):

| Co-morbidity | Start of screening | Screening methods and frequency |
|---------------------|-----------------------------|---|
| Growth failure | At diagnosis | Every 6 - 12 months: Auxology. |
| Thyroid dysfunction | At diagnosis | Every 1 - 2 years: Thyroid function and serum anti-thyroid peroxidase antibodies. |
| Coeliac disease | At diagnosis | Every 1 - 2 years: Serum tissue transglutaminase and/or endomysial IgA antibodies. Antibody-positive patients should be referred to a paediatric gastroenterologist for further evaluation. |
| Lipodystrophy | 6 months' diabetes duration | Every 6 months: Examination. |

TABLE 7: RECOMMENDED SCREENING PROGRAMME (CO-MORBIDITIES) FOR CHILDREN WITH DIABETES (INTERNATIONAL SOCIETY FOR PEDIATRIC AND ADOLESCENT DIABETES)

RESOURCING HEALTHCARE FOR CHILDREN WITH DIABETES

The management of childhood diabetes, especially T1DM, is extremely complex. Young children with diabetes should be managed by a multidisciplinary team (MDT) lead by a doctor specialised in paediatric diabetes care.

The Royal College of Nursing recommends that the complement of diabetes nurse specialists (DNS) in a paediatric diabetes service should be 1.0 WTE per 70 diabetic children (Royal College of Nursing, 2005). This means that the paediatric service at Mater Dei Hospital should have two full time diabetes nurse specialists. Currently children with diabetes are supported by the two diabetes nurse specialists who are expected to cater for the entire diabetic population in Malta and Gozo. It is envisaged that additional recruitment of diabetes nurse specialists will allow for a diabetes nurse to be dedicated solely for paediatric diabetes.

All children with T1DM should receive counselling from a registered dietitian with a special interest in paediatric diabetes. Children with diabetes should follow a healthy diet as recommended for children without diabetes. This involves consuming a variety of foods. There is no evidence that one form of nutrition therapy is superior to another in attaining age-appropriate glycaemic targets. Appropriate matching of insulin to carbohydrate content may allow increased flexibility and improved glycaemic control. The effect of protein and fat on glucose absorption must also be considered. Nutrition therapy should be individualised (based on the child's age, nutritional needs, eating habits, lifestyle, ability and interest) and must ensure normal growth and development without compromising glycaemic control. This plan should be evaluated regularly and at least annually. As diabetes care can be very demanding on affected children and their families, these should also be reviewed on regularly by a psychologist. Anticipatory guidance and lifestyle counselling should be part of routine care, especially during critical developmental transitions (e.g. upon school entry, leaving secondary school). Psychologists should regularly initiate discussions with children and their families about school, psychological issues, substance use, obtaining a driver's licence and career choices.

Achieving the appropriate human resource complement to cater adequately for children with diabetes has been identified as an immediate priority. Increasing the competent health professional workforce is a necessary prerequisite to allow service improvements to be made, better support and care to be given to patients and the introduction of innovative services such as an insulin pump service.

Steps will be taken to train and recruit professionals so as to bring the staff complement for the paediatric diabetes service in line with internationally recognised levels.

INSULIN THERAPY FOR CHILDREN WITH TYPE 1 DIABETES

Maltese children with T1DM under the age of 16 years are on the following insulin replacement regimens.

| Insulin regimen | Proportion (%) |
|--|-----------------------|
| Conventional twice-daily regimen (using human insulin preparations) | 25 |
| Multiple daily insulin regimen (using insulin analogues) | 75 |

TABLE 8: CURRENT INSULIN THERAPY (SOURCE: DATABASE MAINTAINED BY PAEDIATRIC DIABETOLOGIST MATER DEI HOSPITAL AUGUST 2014)

The protocol for use within the public health service currently obliges clinicians to start newly-diagnosed children with diabetes on human insulin preparations. This means that all children have to start on a conventional twice-daily regimen, which is considered to have several disadvantages (increased risk of hypoglycaemia, increased risk of poor glycaemic control, higher levels of glycosylated haemoglobin, more adverse long-term outcomes, etc.). Current practice in centres of excellence around the world is to start children with T1DM on a multiple daily insulin regimen (i.e. using insulin analogues) or an insulin pump from the time of initial diagnosis. These regimens are associated with tighter glycaemic control, fewer hypoglycaemic episodes, better quality of life and fewer long-term complications related to diabetes. The vast majority of young diabetic patients on a conventional twice-daily insulin regimen experience poor glycaemic control and/or significant and recurrent hypoglycaemic events.

Children with diabetes will henceforth be started immediately on an insulin analogue if this is deemed the best clinical option for that particular individual.

Any future introduction of an insulin pump service for children must be planned properly in advance and necessitates the availability of sufficient numbers of trained human resources. Failure to introduce a service within the necessary safety standards would place patients at high risk. *A detailed impact assessment of developing an insulin pump service will be carried out.*

PROVISION OF FREE MEDICAL SUPPLIES

Children with diabetes are entitled to receive the following items free-of-charge through the public health service. The provision of these supplies is important to help children and their families in the daily management of their condition and the monitoring of blood glucose several times a day has been shown to improve long-term outcomes.

| Item | Quantity |
|----------------------------------|--|
| Insulin cartridges | As required |
| Insulin injection pens | As necessary |
| Disposable injection pen needles | As required |
| Glucose meter | 1 device supplied at the time of diagnosis |
| Blood glucose test-strips | 4 strips per day |
| Alcohol-impregnated swabs | As required |
| Glucagon vial and syringe | As necessary |

TABLE 9: LIST OF ITEMS PROVIDED FREE OF CHARGE TO CHILDREN WITH DIABETES

SCHOOL

Children spend a substantial part of their day at school. This includes both winter and summer schools. Children with diabetes are also encouraged to participate in out of school activities such as sports activities since these are important to help their integration and self-esteem besides keeping their blood glucose better controlled.

During school hours, most children need to check their blood glucose at least once (e.g. just before their midday break), and a number of them may also need to take an insulin dose just before they eat their school lunch. Most children above eight years are able to understand the basics of diabetes care, check their own blood glucose with their glucose meter and are also competent in self-administration of subcutaneous insulin injections. On the other hand, younger children have to rely on a responsible adult who has some knowledge of diabetes care. Efforts to reach a situation where every school has, at least, one person who is trained and certified competent in performing blood glucose measurement and administering insulin will be done.

ADOLESCENCE AND CARE TRANSITIONING

Diabetes control may worsen during adolescence. Factors responsible for this deterioration include adolescent adjustment issues, psychosocial distress, intentional insulin omission and physiological insulin resistance. A careful multidisciplinary assessment should be undertaken for every child with chronic poor metabolic control to identify potential causative factors, such as depression and eating disorders, and to identify and address barriers to improved control. Furthermore, adolescents with diabetes should receive regular counselling about sexual health and contraception. Unplanned pregnancies should be avoided, as pregnancy in adolescent females with T1DM with suboptimal metabolic control may result in higher risks of maternal and foetal complications.

The time of care transitioning from the paediatric diabetes service to the adult diabetes service is a sensitive one for adolescents with diabetes and their families. Besides the difficulties of managing their diabetic condition which arise during this period, adolescents also need to cope with the changes brought about through the healthcare system as their care is taken over by the adult diabetic service. The change of physician or team can have a major impact on disease management and metabolic control in the person with diabetes with some young adults defaulting follow-up during the transition from paediatric to adult diabetes care services and being more likely to experience hospitalisation for DKA during this period. Organised transition services are important to avoid such episodes.

The transition has been described as “traumatic” since from a relatively sheltered service catering for less than 200 persons, adolescents with T1DM find themselves being cared for in a service that has to cater for around 30,000 persons with diabetes.

There is currently a lack of an established transfer mechanism for the care given to children who are 16 years and under, and to those who are in their late teens. This arises due to the transition of care from the Children’s Clinic to the adult diabetes clinics. At a time when these persons are passing through physical, emotional and lifestyle changes, they are thrust from a familiar atmosphere to one where they are expected to fit in with the rest of the diabetic patient population. The transition should be gradual and the handover done over a period of time. For this reasons *a joint transition care clinic for adolescents with diabetes to move seamlessly from paediatric to adult services will be established.* Adolescents who are 18 and over should be encouraged to attend the clinic alone without the supervision of the parents in order to induce a more congenial atmosphere where the patient can be more relaxed and can open up without the fear of their parents’ opinion.

Adolescents frequent places of leisure where self-management of diabetes may be compromised due to lack of access to a clean, secure and hygienic environment. Operators of leisure and social facilities for young people should be made aware of the needs of adolescents with diabetes and efforts should be made to provide safe facilities where monitoring and insulin administration may take place safely.

CHAPTER 8: RESEARCH AND PERFORMANCE MONITORING

RESEARCH

Diabetes is one of the commonest chronic conditions currently affecting the Maltese population. Research serves to provide the necessary evidence that allows innovation with the objective of preventing or delaying diabetes or its complications. Whilst international evidence is very important in guiding standards of clinical practice, contextual factors profoundly affect incidence and management of diabetes. Therefore, the need for local research that translates and tests international evidence in the local context is required. Much local research has taken place over the past years. Often this is not properly disseminated particularly if it is not published in impact factor peer reviewed journals.

The main priorities for research in diabetes that have been identified in the preparation of this strategy are the following:

- Local genetics of diabetes and interaction between genetic predisposition and risk factors in the environment
- Reasons for increasing incidence of T1DM
- Motivational factors and compliance with diet /treatment regimens
- National Prevalence study of diabetes
- ehealth/mhealth and diabetes management

Through the national diabetes strategy, it is proposed to better organise and coordinate the efforts, resources and expertise available in order to ensure larger more effective research projects. Government bodies, academic institutions, practising clinicians, industry and NGOs are encouraged to come together and pool their resources towards research projects which can have significant impact at both national and international levels

Our overall goal is to promote research into all aspects of diabetes and build an appropriate surveillance system to monitor diabetes incidence and prevalence as well as to document intermediate and terminal outcomes in order to continuously improve the quality of service for persons with diabetes.

PUBLIC HEALTH AND HEALTH SERVICES RESEARCH

Prevalence data for persons with diabetes is sorely lacking at a national level. The last fully fledged prevalence study took place under the auspices of the WHO MONICA project in the mid-1980s. A scientific prevalence study is required to understand the current epidemiology of diabetes in the Maltese islands. The significant societal transitions being experienced also leave an impact on the epidemiology of diabetes. A special focus on distribution of diabetes in society will be incorporated in the prevalence study in order to investigate any inequalities and high risk areas / population sub groups.

This will enable better planning for health services in the area of diabetes as well as economic modelling related to the projected burden of disease. A diabetes prevalence study has been conducted in 2015. The findings from this study will serve to inform further actions and priorities in the coming years in the area of diabetes.

Innovative models of health promotion and health services organisation and delivery for persons with diabetes need to be developed in order to achieve better results and outcomes for individuals and for society as a whole. These include research on the use of technology including ICT to deliver enhanced preventive and supportive services for persons with diabetes.

SURVEILLANCE

There is a pressing need to establish the necessary infrastructure for surveillance of diabetes at a national level. Whilst for other chronic illnesses such as cancer, the existence of a truly national register for the past twenty years has allowed the reasonably accurate monitoring of incidence and outcomes this has yet to be developed for diabetes.

A system of surveillance enables epidemiological trends to become immediately visible such that an appropriate response may be carried out in terms of service planning as well as public health interventions. It may also help to shed light on possible aetiological factors.

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